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Diagnosing and Treating IBS: It Begins With One Simple Question

Announcer:
Welcome to CE on ReachMD. This activity, titled Diagnosing and Treating IBS: It Begins with One Simple Question, is provided by Omnia Education and supported by Bausch Health and Ironwood Pharamaceuticals.

This replay of a live broadcast discusses diagnostic strategies and evidence-based treatment approaches for IBS, emphasizing patient-centered care and subtype-specific therapies.

Ms. Orleck:
Good morning, everybody. Really excited to be here. Unfortunately, Dr. Cash had some travel issues and will not be able to make it live, but he will be joining us virtually.

So we're really going to hone in on how do we accurately diagnose IBS. And I think this overlaps with so many of the last lectures, just in terms of really listening to our patients, right? And there's a lot of overlapping symptoms, so I think we'll have a quite nice overlap here. But really talking about one question that it starts with, meaning, how can we actually ask our patient the right question to really start to think about, could this be IBS? And then hopefully you'll walk away really understanding the shift we've seen with diagnosing IBS.

So just like the other talks, here is a link to your preassessment questions. Just make sure that you use this QR code to join this session.

So again, I am Kim Orleck. I'm a PA from Atlanta, Georgia. I've been practicing in the GI space for over 16 years. Again, I'll be joined virtually by Dr. Cash.

So here are both of our disclosures.

And the learning objectives. So we are going to identify the components of the diagnostic process for IBS. Again, we've seen the shift; I've seen it personally shift in my time as a clinician. We're going to talk about evidence based clinical tools to be able to positively and accurately, with confidence, diagnose our patients with IBS-C, as well as patients on the opposite side of the spectrum with IBS-D. We're going to discuss the most important factors that influence satisfaction with medical care for women with IBS.

So starting off, and I really love this slide, IBS is no BS, because similar to what you guys talked about with your patients, right? These patients very often that I see, they've seen 3, 4, 5 providers, and they're never actually given an answer for their symptoms. All they're told is, 'Well, this test was negative. This test was negative,' or 'it's in your head,' right? And they start to really believe it's in their head and that there's nothing wrong with them. They're very frustrated. And we're going to talk about the frustration that we see from the impact of these symptoms to the patient.

So what is IBS to start? So it is a chronic disorder of brain–gut interaction that is characterized by chronic abdominal pain and altered bowel habits. And I really want to call out the pain component, because we all see women who have constipation—chronic idiopathic constipation, other types of constipation. The biggest difference between that and IBS is this pain component. And so again, pain is a critical part. As we move on to diagnosing, this is a critical part of the diagnosis.

The other important thing we're going to really delve into is, what does it mean that it's brain–gut? Well, what it means is we're not going to find any structural or biochemical cause for this condition, and so we're going to talk about the bidirectional relationship of how the brain impacts the GI tract and the GI tract impacts the brain. And I always have this conversation with my patients that they can understand the why. We'll talk about the really complex pathophysiology. But again, we know it's this bidirectional relationship of the brain and gut.

It is the most commonly diagnosed GI condition, so about 30% of GI referrals are for patients with IBS. So we look a little bit more at the epidemiology and the cost, the prevalence in the U.S. in studies ranges anywhere from 7 to 16%. But when we put that into numbers—quite large—35 million Americans are impacted with IBS. And again, we'll talk about this, but there are so many patients out there that have not been diagnosed, and we'll talk about why.

It is more prevalent in women. But I want to call out while this is a women-focused conference, that we do know that about 40% of these patients are men. So don't forget that this still exists in men. And I think we've shifted so much to remember the women that often we forget how common this can still be in men.

The majority of these patients are under 50, so usually this is a diagnosis of adolescence and younger adulthood. And so as we talk about that age, it's really important we'll make sure that patients are up to screening if they're 45 and older with colonoscopies. But again, it typically is occurring in these women of younger age.

And then the cost. So there is a very large direct medical cost, but we'll also talk about the indirect medical cost. When we look at direct—again, studies vary—but anywhere from $2 to $6, there's actually some studies going up to $10 billion spent in IBS.

So symptom burden, and we're going to look at burden from a lot of different ways. So first, when we look at health status, when we look at personal activities, we see, on average, 8 days a month. Right? So think about this—almost 1/4 of their days—and this means patients were missing out on social activities, patients who are not going out to dinner or socializing with family or friends, they're not able to keep up with work or things within the house just to keep their family or their home going.

When we look at in terms of actual school and work, on average, it interferes with their productivity 11 days a month. So we'll talk about the fact that these patients are often absent from work, but they also have a very high amount of presenteeism. So they are there, but they're not able to do their work well because of their symptoms and how much this is impacting every day.

And then really an astounding statistic you can see, and we'll talk more about the patient burden, but up to 30% of these patients have actually contemplated suicide as a result of their symptoms. And in addition to that, we'll talk about the overlap with mental health, but we see very high percents of overlap in patients with anxiety and depression, so numbers of 40 to even 50% overlap in these patients with IBS.

So as I alluded to, we know despite the fact that we're learning more about IBS and how common it is, it is still an underdiagnosed condition. So when we look at diagnosing in the primary care setting, it's the 7th most common diagnosis. But again, up to 75% of these patients, they haven't actually been diagnosed. And I see this all the time. So these patients walk in, they have pain, they have bowel issues, we'll talk more about their symptoms. And when I ask them, they've seen 3, 4, 5 providers, and they're told we'll try this over the counter, try the probiotic, try fiber, try an osmotic. They do a whole bunch of tests, but nobody actually sits down and says to them, 'This is what you have, and this is what we can do to help with your symptoms.'

So why is that? We're going to talk today about how we diagnose patients with what's called a positive diagnostic strategy. When I started practicing, IBS had to be this diagnosis of exclusion. So we put these patients through a huge workup. These patients used to all get colonoscopies, they got CT scans, they got ultrasounds, and then after we excluded all of these other diagnoses with a very expensive and very long time period to get them to IBS. Now, we have thankfully shifted, with all of our guidelines, to this positive diagnostic strategy.

The issue is, while we have started to learn this and really focus on it in GI, these guidelines, these criteria, are still not being applied throughout clinical practice. So we'll talk about the Rome criteria.

When we look at provider statistics, only about 2 to 36% are actually aware of this criteria. This is the criteria to diagnose IBS, and only up to 21% actually use this criteria. So about 80% of providers are either not even aware or not putting this into their clinical practice.

Hence, patients continue to have symptoms and they don't even know what they have.

I think this is actually understated, that it is 4 years to the average time from IBS symptom onset until they actually get a diagnosis. And again, there's a lot of reasons behind this. One of the many is really frustration. So 67% have had symptoms for more than a year before they even see a healthcare provider. And then again, very often, it becomes tests but no actual explanation. It becomes a lot of the over-the-counters that we'll look at that really don't help these patients.

So looking further at disease burden, it really affects every aspect of these patients' life. So we know again, even if they're at work, they have a lower quality of work. They're not actually present and able to complete their work. There's a loss of income, because, as I mentioned, they are often missing about 10 or 11 days of work or school a month.

There's a significant burden at home. So many times, the patients will tell us, 'Well I can't go to the ball field because I don't know where the bathroom is and I'm not going to watch my children's activities. What if I have to go and there's nowhere to go?' So again, they're missing social outings. They're missing being part of their family. It really plays a burden on the entire family.

The direct costs of medical is, of course, all the visits to urgent care, to emergency rooms, to primary care, and to specialists, and as I mentioned, a lot of unfortunately unnecessary tests that are still happening because, again, providers don't know about and they're not using this positive diagnostic strategy with the Rome criteria.

And then there's also the indirect costs. So again, whether they're at work and they're not able to do their job well, or they're not even able to make it to work, and then the increase in benefits from a healthcare standpoint.

Thankfully, we continue to have a lot more research in this area. But of course, that also takes money to continue to have research. We'll talk about pathophysiology. We've learned a lot over the years, and we continue to learn more about why do patients have this disease. Thankfully, Dr. Cash will really review medical therapy. We've seen an increase in therapies, thankfully. But again, it costs a lot of money to get these new drugs. And then thankfully, we continue to have updated guidelines, so a lot of work behind the scenes to try and improve and standardize care.

So I really want to call out this first part on the left-hand side, the primary reason patients seek treatment—abdominal pain, abdominal discomfort, and bloating. And so again, interestingly, we don't even see anything about the bowels, right? So these patients almost always have constipation or diarrhea, or they have what we call IBS-M—they're mixed. But it's not usually what they're coming in for. They're not coming in to see us saying, 'I have constipation.' They're not coming in saying, 'I have diarrhea.'

And so this comes down to how we ask these patients questions. Again, what is that first question? And we'll talk about this. But as you can see, it is some element of pain or discomfort or bloating that is really pushing these patients to seek treatment and come into healthcare providers.

It is then on us to really do our job and ask these patients about their pain. Is it associated with your bowels—which we're going to talk about? Do you go to the bathroom every day? Are you actually emptying your stools? Does your pain get better? We'll talk about this. But their pain is typically associated with their bowels. It either gets better or it gets worse associated with that bowel movement.

On the right-hand side, we see satisfaction. And despite the fact that we have gotten more therapies, and there's increased research on this, even the patients who are taking an approved therapy—which Dr. Cash is going to talk about these therapies—we still only see that 1/4 of patients on a prescription therapy for IBS are very satisfied with that therapy.

Again, a lot of reasons to this. We know—we'll talk about this—but there are a lot of options for therapy now. So sometimes it's on the provider to keep up with these new therapies. If one therapy isn't working, we have to offer them a different therapy. Sometimes we have to do adjunct therapy.

Again, we'll talk more about the brain–gut, but sometimes there are certain medicines that target the pain, the bloating, the bowels, but there's still the element of brain–gut, and we often use, as you've talked about here, things like TCAs and help with neuromodulators.

As we move down this list—and again, this is where the frustration comes with these patients. They have tried so many over-the-

counters. They've tried so many eliminations, so many different diets. They're constantly on Amazon, they're buying supplements, they're following social media. They're doing all of these things to try and get relief. But when we look on average from all of these over-the-counters, and even some of the things they're advised to try from providers, we see about 10 to maybe 20% with these over-the-counter non-prescriptions actually giving them satisfaction.

And we're going to talk about non-prescription laxatives. And my big callout for non-prescription laxatives—I know Dr. Cash will talk about this—is non-prescription laxatives have a great place for the bowels, right? We use things like polyethylene glycol very often. It helps with bowels, but it doesn't help with pain. And so again, to get to that point, pain is almost always what is driving these patients to want to get care, and so we don't want to give them something that is only going to help with the bowels. It's not going to help with what they're really looking for.

So this is one of the most common surveys well-known in GI related to IBS. So this is the IBS in America survey, and there's been multiple reiterations over time, but essentially it is a very large survey that is actually sent out to look at patients who are properly diagnosed and living with IBS. And this really shows the impact of this disease on their day-to-day.

So what we see is 72% of these patients, they don't feel like themselves because of their symptoms, 69% say they don't feel normal, and 69% say it's actually holding them back from reaching their full potential.

When we look at IBS-C—so more of the constipation side—these patients are spending money on over-the-counters. We just talked about it, it often doesn't work, so they're frustrated. Many of them are actually avoiding not just relationships, but sex because of their symptoms, and they don't feel comfortable with their significant others.

When we look at the responses from those with diarrhea, again, as I mentioned, I hear this all the time. They're missing out on social situations because they can't get far from the bathroom. They're nervous commuting to work. They know every single bathroom along the way. While IBS is not IBD—inflammatory bowel disease—these patients often feel like our IBD patients. They literally have to track bathroom to bathroom. They also find it difficult. Their symptoms are very unpredictable, so they don't know when they're going to have a flare. They don't know when it's going to hit them, and they're going to be at a meeting, and they're suddenly going to have pain, they're going to have urgency, they have to run to the bathroom.

So all of this equates to the majority of these patients have a lot of emotions, but frustration is their biggest one. In addition to that, 1/3 of these patients describe feeling down, depressed, and they're even hopeless, and they feel these emotions on more than half of the days when we look at the past month while they're taking this survey.

Okay, so if you guys can take out your phones, we're going to do a few questions, leading into some more information about what causes IBS.

So, a 38-year-old woman with IBS who reports frustration that her symptoms were dismissed by prior providers. She says, 'They told me it's in my head.' Based on current evidence, how are we going to respond? Are we going to explain that it is a functional disorder with no proven physical cause? Are we going to acknowledge her experience and ask how IBS affects her daily life? Are we going to perform repeated imaging tests to rule out a structural disease? Or are we going to start her on a low FODMAP diet?

And this is kind of a segue, because we haven't answered all these yet. Awesome. So, as I mentioned, a lot of these patients are frustrated. They've seen so many providers. We really first want to acknowledge—we want to acknowledge that their symptoms are real. Again, we're going to get into the pathophysiology in a minute, but we really want them to understand: I believe you. We understand you hurt.

So this is actually my favorite slide—what causes IBS? So it's really, really complicated, and we know that there is not just one thing. And as I mentioned, we're still doing research on this. We've learned a lot, but it's not completely understood.

So what do we know? As I mentioned, we know it's brain-gut. We know that there's going to be no structural or biochemical findings, but there's a lot of things that lead to IBS.

Visceral hypersensitivity—and this is where I spend the most time with my patients. You guys just did a great job. We have 10–15

minutes, right? But the biggest thing for these patients is they hurt. I just showed you this—they bloat and they hurt. And so these patients have often been told, 'Well, everything is negative, it's in your head.' They start to really think they're crazy.

And this is how I explain it to my patients: we all have stool and gas in our intestine. Hopefully none of you have IBS. And so you are not sitting here hurting because of the gas and stool in your intestine. We know that patients with IBS have increased brain-gut connection, increased awareness of pain, so when they have that same amount of stool and gas in their intestine, it is stretching on the lumen of their intestine, and it hurts. That's that visceral hypersensitivity. And I explain to the patient: we can do every test on you—we can do CT scans, we can do ultrasounds, we can put you through a colonoscopy, but we're not going to see that. So we know that that pain is real, and acknowledging to the patient that we understand they hurt, and it is not just in their head—while it is brain-gut, it is a true brain-gut connection.

GI motility plays a part. So with constipation, obviously there's slow motility. With diarrhea, there's faster motility, and that is related to also fluid secretion.

We know that there's increased permeability. So essentially, we know that the tight junction gaps are different in patients with IBS, and this allows a low level of inflammation.

We know there's a genetic risk factor. We know that patients who have a first-degree relative with IBS have an increased chance of having IBS.

Again, brain-gut. We know there is an overlap with a lot of mental health conditions. Patients who have abuse or trauma as a child have an increased chance of IBS. There's overlap with anxiety and depression.

Gut microbiome is really interesting. So about 20% of patients with IBS have post-infectious IBS. This can be a bacterial infection, it can be viral, it can be anything that happens that then they have this sudden onset. And so we know that microbiome, the gut flora, plays some sort of element. We also know patients who have an infection and go on antibiotics—those antibiotics increase their risk of IBS, because again, it changes their gut flora, their microbiome.

So again, it's complicated. It's not one thing. But I think the best thing we can do as providers is to explain this for patients so they understand the why, and they can start to really understand the therapies.

We're going to talk to them about that. Dr. Cash will talk about how it really targets the etiology—it's not just a bandage to their symptoms, but it really tries to stop things from where they're starting.

So again, this really just shows the bidirectional emphasis on it's not just the brain, it's not just the gut. Okay? So we know it's not always top to bottom, it's not always bottom to top—it goes both ways. Again, when we look back at that last thing, there are a lot of contributing factors, and it's bidirectional between the brain and the gut.

So here's another really important thing: it is really hard to talk to our patients about some of the things we need to ask them about. Just like you guys talked about with endometriosis, right? It's very personal, and so we need to be really comfortable talking to patients about bowel symptoms. Very often, you can feel the hesitation when patients come in and we ask them about their bowels. They're like, 'But you're not supposed to talk about this stuff.' Well, if we make them feel comfortable, and we're comfortable talking about it, then they're much more comfortable talking about it.

I'm going to show you guys the Bristol stool scale. It often can be a really helpful resource to make this conversation about stool much easier, because there's no biomarkers. I can't do a sed rate, a CRP, a calprotectin and actually give them a diagnosis. It makes it much harder, right? And that's where it goes to us as clinicians, explaining that pathophysiology and explaining to them why they hurt, why they're having constipation, why are they having diarrhea. Acknowledge that it's real. Just because the tests they may have had done, or I'm going to do, aren't going to show anything—it's real. It's there. We're just not going to see it.

And so there is this stigma that it's a neurosis, that it is all in the patient's head.

But it's not. And so we want to try and do whatever we can to remove the patient's fear and concern that there are other conditions, right,

that are driving their symptoms, and really encourage them and really empower them to understand what is driving their symptoms and what they actually have.

Giving them that diagnosis is so important, right? And as I mentioned, the most common thing I see is these patients are just told, 'Well, it's not this, it's not this, it's not this,' and they want to know, 'What do I have?' And so taking time to really explain that to them is so important.

So, the scoop on talking about poop. So we're going to get into how we diagnose it, but it's all about talking about their stool changes. And so we're going to talk about the Rome criteria and what this looks like. As I alluded to, abdominal pain—the pain is related to their bowels. This is the hallmark of IBS. It helps often to use the Bristol stool scale, which I'm going to show you.

And then it is on us to also ask about what other symptoms they have, what we call these abdominal symptoms, and this includes bloating. Bloating is so, so common in these patients. We want to ask these patients what other symptoms they have so that we can try and improve all of their symptoms.

So this is the Bristol stool scale. I'm assuming most of you have seen this. So this can be really, really helpful, particularly for patients who aren't really comfortable describing their stool. As I mentioned, it's common. So over 4% of Americans meet the Rome criteria that we're going to talk about. More than 30% of these patients fall on the side of constipation. A really important thing to remember is to be able to get this diagnosis and put them into buckets of subtypes—it's not 100% of their stools, okay?

So for a patient to have IBS-C, what that means is more than 25%, more than 1/4 of them, need to be type 1 or type 2. These are usually what patients describe as hard, pebble-like, rabbit pebbles, things of that sort, right? But they can still have diarrhea, and very often they do. These patients have overflow diarrhea. So they're constipated for days and days and days, and then they have to empty out. And so they report these intermittent days of, 'I might go 3, 4, 5 days with hard, teeny stools, and then I suddenly have all this overflow diarrhea.' So don't think they can't have IBS-C just because they have some element of loose stools.

On the opposite end, have IBS-D—more than 25% need to be mushy, loose, watery, more of these 6 or 7s. But they can still have constipation in between.

And then our IBS-M is the ones that have more than 25% constipation, more than 25% diarrhea.

Okay, so again, the big takeaway is the majority of their stools put them into their subtype, and that's how we want to classify them. It's also important to remember these patients can change subtypes. So they might go from IBS-C to IBS-D, and they might go back to IBS-C, and that's not uncommon.

So how do we diagnose them? This goes back to what is that important question, and it goes so much to that history. So the first big thing I mentioned is these patients are going to have pain. Okay?

We're going to move on the next slide into that Rome criteria that most clinicians don't know about. And even if they know about it, they don't use, but you'll see the importance of pain. Pain is the primary question. So we're going to take a great history, we're going to do a thorough exam. We're going to make sure that there's no alarming things on exam like an abdominal mass. We want to do a good digital rectal exam to make sure that we assess for sphincter tone. We want to make sure there's nothing anatomically that we note abnormal on a good rectal exam that can also increase our thoughts of a possible pelvic floor dysfunction, more than just IBS.

Then we'll move and talk about the Rome criteria, which includes that diagnostic strategy—that positive diagnostic strategy based on symptoms. We're going to rule out alarming features, and then with confidence we are going to tell the patient, You have IBS, and now we are going to get you on a therapy and we're actually going to get you feeling better.

So, Rome IV criteria—what this means: patients have recurrent abdominal pain. It occurs at least 1 day a week on average. It has been present for the last 3 months, and it's associated with at least two of the following:

It is related to defecation. So patients will often say, 'My pain gets worse right before bowels.' Very often it gets better when they have a bowel movement. So this is the question: Is your pain related to your bowels? Does it get better or worse before you have to go, or do

you get relief after you have to go?

The second one: It's associated with a change in the frequency of the stool and/or a change in the form of the stool. So while they have to have had symptoms during the last 3 months, their symptoms have to have been present for at least 6 months in order to give them this diagnosis. So it is a chronic diagnosis. As I mentioned with the history, we want to make sure we have symptoms during the last 3 months, present for at least 6 months.

We want to ask them, Did they have any recent infection? Very often we get the story of, 'I had a gastroenteritis. I traveled to Mexico, and I got that horrible 24-hour bug, and then it was never the same. My bowels have stayed diarrhea,' or 'I developed sudden constipation.' That's our post-infectious IBS patient. So that history is really important.

We're going to move on to alarming symptoms in a minute that we're going to rule out.

We want to ask about medications—are they on meds that are causing their diarrhea or causing their constipation, or changing their subset?

Again, this overlaps with conditions. We heard this morning about the overlap with endometriosis. We also see it overlap with fibromyalgia, interstitial cystitis, migraines, chronic pain, and again that anxiety and depression that often overlaps in these patients with IBS.

I mentioned the exam. It's so important—we want to lay hands on our patient, and we want to do that rectal exam. We want to make sure that we are not missing any sort of anal-rectal mass or things of that sort. And again, you can elicit, do they have a normal squeeze function? And it can raise your suspicion for a pelvic function disorder.

So, alarming features is the next part. Almost all of this is done by a great history. Does the patient have a first-degree relative with colorectal cancer, particularly at a young age? Do they have somebody with Crohn's or ulcerative colitis that increases our suspicion of having IBD? Or is there a family member with celiac disease? All of those warrant a further workup.

Do they suddenly have new symptom onset over the age of 50? Again, this usually hits younger patients. This typically does not suddenly happen at that age.

Do they have weight loss? Do they have nocturnal stools? These are things that we want to do more of a workup. These are alarming. These are not typically what is seen in IBS.

The other one you can see with blood under the stool is iron deficiency anemia. So this is going to lead into the workup part that we'll come back to, but at minimum you want to do a CBC on these patients.

So as I mentioned, positive diagnostic strategy, I always explain this as three buckets. That first one is, we've taken a really great history, and we feel comfortable and confident that their symptoms fit the Rome criteria. So pain, it is related to bowels, change in stool form, change in stool frequency.

Number two, we are ruling out those alarming features. Almost all of it is in a history, but it leads into the third part, which is a limited diagnostic workup. Again, we do not need to do an extensive workup. What does this mean? Well, all patients need, at minimum, a CBC. We want to make sure they are not anemic. If they are anemic and we don't have another reason for it, that obviously comes back to GI of, hey, we want to do an endoscopic evaluation. Okay?

The other thing is, if they are over 45, we want to make sure they are up to date with age-appropriate colorectal screening. So they've had that up-to-date colonoscopy.

When these patients have an element of diarrhea, whether it is IBS-D, where more than 25% at least again is diarrhea, or they fall into this mixed category—but again, at least 25% are diarrhea—we want to do a CRP and a stool calprotectin. For those of you who don't live in the GI world, stool calprotectin is more sensitive and specific than leukocytes in the stool, so it is an inflammatory marker that is very sensitive and specific for IBD.

So by not doing a colonoscopy, with confidence, if they have a negative CRP and a negative calprotectin, we can tell these patients it is very unlikely you have IBD. I do not need to put you through a colonoscopy. TTG, IgA and serum IgA to make sure that we're not missing celiac disease.

And then if there's any question in these mixed patients, and even sometimes in the constipation patients, we can get a KUB and just see: is there significant stool burden? That really makes us think that this is truly a constipation patient.

And then I do want to call out—you'd see that stool studies are not really on here. We want to do Giardia if patients have risk factors. If they've been on recent camping, lake exposure, daycare exposure, things of that sort, we can consider Giardia, but routine stool tests are not recommended. We do not see a significant yield. These patients have chronic symptoms. They didn't suddenly just get an acute infection.

Obviously, if there are risks for acute-on-chronic symptoms, you're thinking of things like C. diff because they were on antibiotics—go for it. But routinely, again, we are not recommended to do stool studies in these patients.

And then you can consider bile acid testing if patients have diarrhea predominant. So think of this in those patients who have had a cholecystectomy, patients who have had an ileal resection, and so they can't absorb in the terminal ileum the bile salts. Those are patients we want to think about that bile acid testing.

On the constipation side, aside from that up-to-date screening colonoscopy and that CBC, there's no other special testing. Again, if they are refractory to therapy that Dr. Cash is going to talk about in just one minute, we can consider working them up for pelvic floor dysfunction with things like an anorectal manometry and MR defecography, and getting them in for biofeedback for the constipation support.

Dr. Cash:
Well, thank you, Kim. And my sincerest apologies for not being able to be present.

But thanks to technology, we're able to do this.

The things that I want to reiterate that she mentioned was and the things that I teach with IBS—is think of this. And we talked about IBS as a disease process for, I think, much too long, and my own thinking has changed on this. But really think of this as a syndrome of symptoms.

You saw the suspected pathophysiology. Some patients have multiple of those pathophysiologies. There are others that I'm sure we still haven't even discovered yet. We have not been able to really decode the black box of GI motility, the microbiome, microinflammation, et cetera. We understand in general how the GI tract works with regards to motility and inflammation and immunology, but we haven't really gotten down to being able to fine-tune it, as such. We're really very much like the ape on and for those I'll date myself, but the movie where the ape is hitting with the femur bone.

So let's move on and talk about how we treat this. And Kim mentioned the multiple symptoms of irritable bowel syndrome—the psychological symptoms, of course the abdominal symptoms and the bowel habits. And it really is an integrated issue, meaning that there are aspects of patients' lives that are affected that need to be addressed, much like the overlapping conditions that she mentioned.

So as I go through this, we're going to talk about the role of diet. We're going to talk about the role, of course, of medical therapy. And when we treat IBS, we're really largely treating the symptoms. There are a couple therapies that may actually treat some of the pathophysiologies that we're suspicious of with regards to irritable bowel syndrome—some for diarrhea, some for constipationbut generally we're treating symptoms.

And then finally, the behavioral aspects and behavioral components. So treat this as an integrated disorder, and I'll show you data that shows that actually, the outcomes for your patients and healthcare resource utilization are significantly improved when we do that instead of compartmentalizing this and just treating diarrhea, just treating constipation, just treating abdominal pain.

So general principles—Kim's already gone over this. I'll go over it very quickly. Exclude organic disease. Always have to keep in mind in the very back of our minds, could this be inflammatory bowel disease? Could this be a malignancy? Could this be celiac disease? Some other organic gastrointestinal disease?

Irritable bowel syndrome is an organic gastrointestinal condition. There is something organic causing these symptoms. And I used to say, Well, if you rule out organic disease, then it's got to be irritable bowel syndrome, or irritable bowel syndrome is something that occurs in the absence of an organic disease. I've changed my thinking and my teaching on that—there's an organic cause for this, we're just not smart enough, or don't have the right tools to figure this out.

But rule out the less common but more significant for patients, organic diseases that might lead to significant morbidity or even mortality. Again, not a diagnosis of exclusion. You can get much of that history and rule out those alarm features, and you can have great certainty if the patient meets the Rome criteria that they do in fact have irritable bowel syndrome.

The key here is that you follow up those patients, reevaluate those patients. If they're not behaving like you think they should in terms of their symptom improvement, or there's something that does pop up that's alarming, then of course, go after that and investigate it. Establish that rapport, reassure, educate, categorize the IBS subtype, because that's really going to dictate your treatment of their symptoms.

And then we'll talk about first-line therapies, the OTCs, non-FDA-approved therapies as well, and then off-label therapies and psychological therapies as we move forward.

So when we think about initial treatments—and I've divided this up into IBS with constipation, IBS with diarrhea—of course, we're going to treat those almost diametrically differently. In terms of prevalence, it's about 1/3, 1/3, and 1/3 for IBS-C, IBS-D, and then IBS-M.

There is some travel between those subgroups. So patients can switch or move from a constipation-predominant IBS to a more diarrhea or a mixed, or back and—it's more common to see somebody move from mixed to one of the others. Often we'll call somebody IBS-M, and it really turns out that they have primarily constipation with overflow diarrhea. And that's as Kim alluded to, getting an abdominal film.

You really have to take a really good history. Somebody comes in, says, 'I have episodes of diarrhea, but then I have constipation.' Really pin them down. Do you have 4 or 5 days of constipation, then you have 1 day of diarrhea? That's probably IBS-C with overflow diarrhea—the colon just says, finally, get out—and they have a day of diarrhea, and then they're back to their constipation.

So for that 1/3 of patients with IBS who have constipation, get them to engage in some physical activity if they can. Now, this is not always practical for some patients, but just engaging in physical activity is a good therapy for constipation in general, not just irritable bowel syndrome. It's also perhaps good for mental health.

Look at those medications, as Kim mentioned. Increasing dietary fiber intake, especially with soluble fiber or a fiber supplement. Now, it's much more practical for people to do a supplement of fiber, such as a tablespoon of Metamucil or psyllium. Konsyl, Benefiber—I like Benefiber. That's my go-to fiber, it seems to cause a little less bloating. Avoid those insoluble fibers for patients.

But you know, when patients come in and say, 'Oh, I eat a high fiber diet,' get that diet history, if you can. But encourage them to do a supplemental 1 or 2 tablespoons of fiber. Start slow and increase slowly, but that often can help with just general constipation.

And then over-the-counter laxatives. And what we're talking about here are things like bisacodyl or Dulcolax, MiraLAX, or PEG 3350.

Any of those types of OTC therapies there's a myth that those therapies can actually harm the colon with long-term use, or people can become physiologically dependent on them. That is not true. There certainly are people who can become psychologically dependent on multiple different laxatives, including prescription laxatives, but these are safe therapies, and they can help promote laxation.

Now, what they don't tend to do is, they don't tend to help, as Kim mentioned, the abdominal pain. When we look at studies of these OTCs, there are not a lot of studies of over-the-counter therapies, but generally, they've not been shown to reliably improve the abdominal symptoms, meaning the pain and the bloating that patients experience. But that doesn't mean that they're not worth trying.

So common OTC therapies—I've already mentioned fiber—uh modest benefits for global IBS symptoms. That's the whole compendium of IBS symptoms, not just the bowel habits. But it is strongly recommended by the American College of Gastroenterology for overall symptom improvement. It's cheap, it's widely available, very low side effect profile. The most common side effect the patients will complain about is going to be bloating.

And there are strategies in different fibers to use. The more finely cut the grain—and these are generally psyllium-based fibers the less bloating the patients have. I mentioned Benefiber that's my favorite—but some people may tolerate one fiber better than another.

Generally, we're looking at dietary or total daily intake of 20 to 30 grams of fiber. The average American diet has about 10 to 15 grams of fiber. Supplement that with 1 or 2 tablespoons of fiber, you're getting up to 25 to 30 grams of fiber daily. Reasonable to try if patients haven't tried. If they say they've tried it, ask them how much they've tried. Did they do a teaspoon? Did they do it 3 times a week? Did they do it just when they got constipated? And you'll often find that they really weren't adherent with proper dosing.

Osmotic laxatives, I alluded to those as well—improve stool frequency. These are go-to therapies in pediatrics as well as adult medicine for people who are constipated. And they are very good therapies for improving constipation. As I mentioned, they don't seem to improve abdominal pain reliably. Sometimes promoting bowel movements will improve abdominal pain. That's a reason to use these first line. Often, I'll use fiber and osmotic laxatives together to see if we can get a synergistic effect.

ACG, in their guidelines, gives PEG (polyethylene glycol) a weak recommendation for overall symptom improvement. Again, that's the whole compendium of GI symptoms, but these are very reasonable therapy for constipation and a good first place to start.

Same thing for stimulant laxatives. Now, recognize that these can sometimes cause abdominal pain because they are causing motility, they're increasing motility, they're increasing squeeze. So again, the first question that we ask with regards to these bowel habits is: Are you experiencing abdominal pain associated with these abnormal bowel habits? So these can, conversely, sometimes make patients' symptoms worse. There's no randomized controlled trials that have been conducted with stimulant laxatives, but not unreasonable to use in some patients. You just have to try these things. If they don't work, you can simply stop them. And they have a very low side effect profile.

Very busy slide here. I'm not going to spend time going through each and every box, but Kim alluded very nicely to the psychological impact that irritable bowel syndrome has, and this is true of really any chronic condition. You all have talked about multiple chronic conditions already in this conference. Irritable bowel syndrome is no different. Other aspects of GI that were mentioned—inflammatory bowel disease, celiac disease—all would fit into this. Chronic conditions, chronic symptoms, take a psychological toll.

And there is a place for psychological therapy. The ones that we tend to use in GI—and it's not restricted to irritable bowel syndrome—would be things like gut-directed hypnotherapy, cognitive behavioral therapy, mindfulness meditation. These have all been shown in some really relatively well-done studies to significantly improve IBS symptoms.

And essentially, the simplistic way of thinking that I have with regards to these therapies is it helps our patients learn how to pack away or deal with their symptoms in a cognitive or a more cerebral aspect. It diminishes their catastrophizing. They're able to really kind of sequester that symptom experience, and that helps them with their symptom experience. Of course, we still want to improve their symptoms and diminish their symptoms, but it's, again, an amalgam of this therapeutic approach.

This is another busy slide that I just included in the deck because, as clinicians and prescribers, we like to know how things work. So when we think about treating irritable bowel syndrome—and again, we're talking about IBS with constipation here—we have really three different areas that we can treat. One is the luminal area, the luminal GI tract, that's shown on the left.

Then you've got basically the machinery of the GI tract, which is the nerves and the muscles, and that's shown in the middle. That's where those therapies work. And included in those blue boxes are some of the important neurotransmitters and neurohormones.

And then we've got the central nervous system. Kim alluded that this is a disorder of gut-brain interaction. There's a pain processing disruption in patients who have irritable bowel syndrome in terms of how they manifest or experience pain. That's what some of the psychological therapies can help with as well. So that's shown on the far right.

So think of this as kind of three compartments. Most of our therapies are going to be working on the luminal side of this picture.

And what we've included in these purple boxes are some of the FDA-approved prescription laxatives, as well as things like probiotics and symbiotics. And some other therapies that are not FDA-approved for irritable bowel syndrome that are shown on this slide. I thought this would be a helpful slide just to kind of conceptualize how things work.

When we look at kind of the gamut of over-the-counter therapies as well as prescription therapies, I've already alluded to the fact that a lot of our OTCs—the laxatives that we're going to use for IBS-C—can help with defecation symptoms, the constipation the patients are experiencing, that Bristol stool form scale 1 and 2 stool, or the infrequent bowel movements, or the straining. But they don't improve abdominal symptoms reliably that's bloating, abdominal pain. That is not a reason not to give them a try, but just recognize that you're not going to hit a triple or a home run every time you use those therapies.

And that's where the prescription therapies have been a proven role. These have been rigorously tested as part of their FDA approval process, looking at endpoints that include not only the defecation symptoms but also the abdominal symptoms that these patients experience, and they have been shown to improve those symptoms.

And when we talk about the FDA-approved therapies, we've really got four in the IBS-C area. We've got three secretagogues—that's plecanatide, linaclotide, and lubiprostone, and then we have one newer therapy that's termed a retainagogue, and I'll explain why—and that's called tenapanor. All of these have been shown to improve not only bowel habits but also abdominal symptoms and are FDA-approved for IBS with constipation.

So again, this is just a timeline of when these drugs were approved. In terms of their mechanism of action, think back to that slide I just showed you. These are working on the left side, the luminal side. All of these agents are not significantly absorbed into the blood, which gives them a degree of safety in terms of other organ effects or side effects.

The oldest of these therapies, which is the secretagogue, is lubiprostone. That's a type 2 chloride channel activator. It opens up chloride channels and brings chloride and sodium and fluid, namely water, into the gut lumen. The GCC agonists, linaclotide and plecanatide, are similar. They also bring other ions, such as bicarb, into the gut, and drag fluid into the GI tract.

And then finally, the retainagogue, tenapanor, works by trapping dietary sodium in the gut, up to 3 grams per day. And if you trap dietary sodium, the body wants to trap chloride and then also trap fluid, because the body likes a balance. It likes an electrochemical balance, and it likes an osmotic balance. And that also has been shown to improve IBS-C symptoms.

Let's talk specifically about these four therapies. Linaclotide is probably the most widely used of these four therapies. It's a GCC agonist. There are multiple doses of linaclotide and multiple indications. It's approved for both chronic idiopathic constipation as well as irritable bowel syndrome with constipation. It's the only one of these four agents that is approved for a pediatric population—so for young people between the ages of 6 to 17—boy, I sounded old like my father—uh 72 mcg per day for functional constipation. The IBS-C dose is 290 mcg per day. Now, you can use different doses for your patients if you find that they perhaps don't respond as well, or perhaps they have some side effects due to higher doses. The 290-mcg dose was shown in clinical trials to better relieve abdominal pain, and that's why that dose was chosen.

Now, you should advise your patients to take this medication, it's once a day on an empty stomach, at least 30 minutes before the first meal of the day. Food tends to accentuate its effect, so you can use that to your advantage and tell patients to take it with food if you so desire if they don't have as robust a response as you want. It's contraindicated in infants.

And you can see the side effects. The most common side effect that was seen in both the chronic constipation studies as well as the IBS-C studies was diarrhea. And we warn patients about that. It is often transient. It often gets better within a week of continuing therapy.

Remember, patients with constipation may have a little bit of a skewed view of what diarrhea is, so it's important to talk about the parameters around which they may need to discontinue therapy. And I usually will say, if you have an episode of incontinence, or it's causing you a great deal of anxiety or discomfort with regards to your bowel habits, let me know, and we'll come up with an alternative.

We may go to a lower dose. We may go to an alternative dosing regimen. That's really the art of medicine in terms of using these therapies.

Lubiprostone, the chloride channel activator, very similar story. In this case, it's twice-a-day therapy. The dose for chronic constipation is 24 mcg. The dose for IBS-C is only 8 mcg twice a day. And there is some titration that you can do. So it's approved for both of these indications. The lower dose is the one that was studied in females with IBS with constipation. It is only approved for females with IBS-C because those studies that they did that went before the FDA for approval did not have enough men to adequately power the studies to assess the response. It is approved for both men and women with chronic idiopathic constipation. So I tend to use this medication for those indications, and I'll use a variety of doses.

Very safe therapy. Primary adverse event that was seen is diarrhea. You can see some nausea if patients take this on an empty stomach, so they should take it in a fed state. That's opposite of what we just talked about with linaclotide. These two agents work differently. I tend not to use them together because they work similarly, but they do have different mechanisms of action.

We'll talk about plecanatide, which is very similar to linaclotide. It's a GCC agonist as well. The main difference we believe between plecanatide and linaclotide is that plecanatide tends to bind to that GCC receptor in a more acidic environment, namely the small intestine. When the effluent of the GI tract reaches the terminal ileum and the colon, the pH is around 7 to 7.4. There's less binding with plecanatide. So theoretically, this agent was thought to perhaps result in less diarrhea. That's not been proven in any head-to-head studies. I see patients who develop diarrhea with plecanatide. I have other patients who tolerate it better than other agents. So it's really a mixed bag, and you just have to try it with different patients.

Three milligrams per day is its dose for both chronic idiopathic constipation and irritable bowel syndrome with constipation. And just to reframe the difference between chronic idiopathic constipation and IBS with constipation is the fact that patients with IBS complain of abdominal pain associated with their constipation. Patients with chronic idiopathic constipation may complain of abdominal pain, but it's not their central complaint. So it’s a very semantic difference. I often will give patients both diagnoses, and there's nothing wrong with doing that.

Now plecanatide, in contrast to linaclotide, is not approved for that pediatric population. So just keep that in mind—it’s only approved for adults. It is approved for both men and women, and it has a 3-mcg once-a-day dose. And you can take this with or without food. So there’s no food restriction there.

And then finally, the most recent addition, tenapanor. This is that retainagogue that traps sodium in the gut, subsequently traps chloride and then fluid. In terms of its approval, it's approved for both men and women with IBS with constipation, 50 mg twice a day is its dose. The most common adverse event is diarrhea.

And I'm not showing you results of clinical trials with any of these studies. The difference between these therapies and placebo, which is what they were compared to in all of their studies, was somewhere between about 10–12% to upwards of 30% or so. They had different endpoints. Generally, the endpoints of the newest therapies, the GCC agonists and tenapanor, were what we call a composite endpoint responder definition, which is a 30% improvement in pain or more at the same time that patients had an improvement by at least one complete spontaneous bowel movement per week—and that’s a bowel movement without the use of a laxative, in which the patient feels completely evacuated. And they had to do that for at least 6 or 9 out of 12 weeks. So that's the current endpoint that the FDA demands—is that composite endpoint responder—and that's been shown to correlate well with global IBS symptoms. So you can see in terms of recommendations: take immediately prior to the first meal of the day or dinner.

Alright, so let's move on to talking about more bloating and IBS with diarrhea. One of the more common and—and popular things for people to try—we heard about the Mediterranean diet earlier today—is FODMAPs. And if you're not familiar, it's a long acronym. It’s fermentable oligosaccharides, disaccharides, monosaccharides, and polyols. That's a mouthful. Basically, those are poorly digested starches and carbohydrates. These are known and have been recognized to cause a lot of abdominal symptoms, especially bloating and often diarrhea. And it's similar in concept to lactose intolerance. And we've recognized that these foods can impact IBS symptoms, so people have started to do restriction diets on this. It's very popular.

The important thing to recognize is that if you're going to use a low-FODMAP diet, that this be done with a dietitian. So you have to have a motivated patient. It really needs to be a monitored diet. This is not meant to be a forever diet. You do a high restriction for 4 to 6

weeks, you see how patients do, and then you gradually reintroduce foods. So keep that in mind. Don't just send patients to Google and tell them to do a low-FODMAP diet. That's not appropriate for them. That's what I did at the very beginning when all of this started coming out and that was wrong. So a good dietitian is worth their weight in gold, and this needs to be a monitored diet.

Let's talk about drug therapies for IBS with diarrhea. And we're getting close to our time, so I'm going not speak too quickly, but I am going to go relatively fast. So we've got therapies that modulate the gut flora, we've got absorbent therapies, we've got antispasmodic therapies for pain, neuromodulating therapies, and some other things that slow down gut motility. So I'll just talk briefly about a couple things.

One of the common questions that comes up is should we use probiotics? A lot of patients do this for a variety of GI symptoms. Both of our major GI clinical societies—the American Gastroenterological Association and the American College of Gastroenterology—do not recommend probiotics for irritable bowel syndrome. They have not shown convincing, high-quality results for clinically meaningful improvement in IBS symptoms.

Does that mean it's wrong to use probiotics? Absolutely not. Some people feel they derive a benefit. We really don't know what they're doing. Of course, we think they're modulating the gut flora and the microbiome, but we really don't know what these therapies are doing. It's not wrong to use them; you just shouldn't expect, again, to hit a triple or a home run with using these therapies. I do use probiotics. I don't have a specific favorite, but I recommend multi-strain probiotics that contain Lactobacillus and Bifidobacteria.

Another common therapy that's used is antispasmodics, and that includes dicyclomine as well as hyoscyamine. I prefer to use peppermint oil.

This is an antispasmodic that's first-line in Europe. There is data on some peppermint oil preparations in the United States. In fact, I did one of these studies. This is basically L-menthol. It's an antispasmodic, it's a calcium channel blocker, and it can relieve pain and abdominal bloating. This really should be used as an adjunctive therapy. It's not going to improve diarrhea per se, but it can improve bloating and abdominal pain in some patients. And it's fine to use other antispasmodics as well. Peppermint oil seems to have less side effects.

Another busy slide—I won't spend a lot of time, just same concept as the constipation slide: three compartments—luminal, the nerves and muscles of the gut, and then the central nervous system. A lot of different therapies that have been investigated, some of which are FDA-approved.

We have three FDA-approved therapies for IBS. We're going to talk about two of them. Rifaximin is the most commonly used. This is an antibiotic, and as such, it is affecting the gut microbiome. We know that for a fact. We don't know exactly what it's doing. We know that it inhibits protein synthesis, and it's not absorbed, but it has been widely studied for things like traveler's diarrhea, hepatic encephalopathy, as well as irritable bowel syndrome. The dose for IBS is 550 mg, three times a day. This is a non-absorbed antibiotic, so it's really only good for gut infections or perhaps to modulate the microbiome in patients with irritable bowel syndrome.

It's used for 14 days, and there have been numerous studies that have been done showing about a 10–15% difference in terms of improvement of IBS with diarrhea symptoms as well as bloating, with very low side effect profile in these patients. Unfortunately, patient's symptoms often will come back. About 2/3 of patients who respond will have recurrent symptoms, and you'll have to retreat them periodically. But it's a very safe therapy and certainly one that's reasonable to use.

Eluxadoline is the other therapy that we'll talk about. This is an opioid modulator. It actually modulates mu, delta, and kappa receptors of the opioid receptors. As such, it is a scheduled drug. It is not systemically absorbed to any significant degree. It doesn't cause narcotic effects, but it is akin to things like Imodium or loperamide, which can bind to opioid receptors and slow motility. In this case, the mixed modulator effect has some effect on abdominal pain. Now, the dose for eluxadoline is 100 mg twice a day. There is a lower dose for patients who perhaps develop some side effects, such as constipation.

And there are more contraindications to be aware of. You don't use this medication in patients who have a history of not having a gallbladder—so most commonly that's going to be post-cholecystectomy. And also don't use it in patients who have had pancreatic disease because it has been linked to some cases of sphincter of Oddi spasm as well as pancreatitis. Now, it's a rare, rare side effect and you also want to take a drinking history thinking about pancreatitis, so patients who drink more than three alcoholic beverages a day

should not receive eluxadoline. So it's a very good therapy for patients with a lot of fecal urgency in irritable bowel syndrome, but generally we reserve this for patients who don't respond to OTCs, lifestyle modifications, and perhaps rifaximin.

So I mentioned this earlier. I'm going to gloss over this quickly, but just recognize there's some data that shows that using a multidisciplinary or an integrated approach—clinicians, physical therapists, dietitians, psychologists—actually delivers better care for patients. They have better outcomes. They have a more durable response.

A large study called the MANTRA trial, and I'll show you the results and just get to the—the punchline here. These are patients who were randomized either to routine therapy with clinicians such as you and me or a multidisciplinary team approach, and we saw that patients had significantly greater global symptom improvement when they were randomized to that global team approach for both functional dyspepsia as well as irritable bowel syndrome. Functional dyspepsia is kind of an upper GI disorder of gut-brain interaction, so the upper GI form of IBS.

And there's some long-term data with regards to this approach as well, showing that these results can be durable. And I strongly recommend that you try to use this type of a framework when caring for patients: involve your dietitians, involve some physical therapists, especially in patients with constipation that you suspect may have pelvic floor dysfunction. And of course, if you have patients who you believe have some psychological aspect to their symptoms or just need some help dealing with their chronic symptoms, involve a good gut-specific psychologist. They're hard to find, but they do exist. It's an evolving area, becoming more common. But if you can find somebody to help address their psychological care—and if patients are motivated and interested in doing that type of approach, and that's really the key to success. I encourage you to do that.

So with that, I'm going to give you finally just an overview. This is from the AGA guidelines for irritable bowel syndrome. This is not the Bible—you don't have to follow this exact time frame in terms of first-line, second-line, third-line. I often will use some third-line therapy second-line, et cetera. But just an overall compendium of patients with IBS-C and IBS-D. Unfortunately, we don't have anything specific for IBS-M, so we end up trying to treat those symptoms similar to the other groups, find a predominant feature.

But what they've listed here are some of the over-the-counter therapies, lifestyle modifications, antispasmodic pain therapies, and then getting into the prescription therapies. And that's what we tried to lay out during this talk, is start with the cheapest, most accessible stuff first. If that works, that's great. If it doesn't—which it won't in a lot of patients—you're going to need to move to some of the FDA-approved therapies. But keep in mind that integrated approach for your patients, and some of the psychological therapies, especially even low-dose tricyclic antidepressants, which we didn't really talk about, have a real role in patients with these types of disorders.

Okay, so finally, just to conclude, we've highlighted this is a very common and costly disorder of gut-brain interaction with no known cure. It's a syndrome of symptoms with diverse etiologies. It's undervalued, it's underdiagnosed, it is manageable. Use a positive diagnostic strategy; it's not a diagnosis of exclusion. Keep in mind that some things can mimic IBS, and if patients aren't responding or behaving like you think they should, of course, broaden your testing. You start with a good history, that's really key, thorough physical exam, limited and judicious testing.

And then we've talked a lot about available therapies. I won't read this bullet for you for the sake of time, but we've got some really interesting evolving concepts challenging traditional approaches and finding out how we can kind of focus some of our therapeutic approaches to patients based on not only their symptoms, but also their life experiences, their symptom experiences, their psychological profiles—what they seem to complain about, whether it's anxiety, depression, those types of things. It's really showing that we're able to more specifically treat and address these patients' symptoms.

So with that, I'll turn it back over to Kim. Again, I'm sorry I couldn't be there with you in person, but I hope you got something valuable out of this talk, and I really appreciate the opportunity to speak with you all.

Ms. Orleck:
Thanks, Dr. Cash.

Announcer:
You've been listening to a replay of a live broadcast discussing diagnostic strategies and evidence-based treatment approaches for IBS, emphasizing patient-centered care and subtype-specific therapies. This activity was provided by Omnia Education and is supported by

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