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## Seeing Is Believing: The Impact of Direct Visualization of the Uterine Cavity in Diagnosing Abnormal Uterine Bleeding

### Narrator:

This is CME on ReachMD. The following activity, titled "Seeing Is Believing: The Impact of Direct Visualization of the Uterine Cavity in Diagnosing Abnormal Uterine Bleeding" is provided by Omnia Education and supported by CooperSurgical.

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Your experts are Dr. Ted Anderson, Director of the Division of Gynecology in the Department of Obstetrics and Gynecology at Vanderbilt University Medical Center in Nashville, TN, and Dr. Ethan Goldstein, Director of Robotic and Minimally Invasive Gynecologic Surgery at Huron Valley-Sinai Hospital in Commerce, MI.

Here's Dr. Anderson with an overview of abnormal uterine bleeding and the history of hysteroscopy.

### Dr. Anderson:

Let's talk about hysteroscopy. So, hysteroscopy is not new. It really began before the Civil War, back in the mid 19th Century, by an Irish chap, who decided that he would take a look inside the uterus of this bleeding woman, and he found a polypoid sort of structure that he cauterized with silver nitrate. Well, he was kind of considered an innovative disrupter in his time. He laid the groundwork for modern hysteroscopy. But it really sort of floundered for about 100 years, and we didn't see any really uptake on that until we saw Jay Cooper in Arizona really start picking up the gauntlet and using hysteroscopy in a routine sort of diagnostic way, but it wasn't until really the '80s that we began to see routine incorporation of hysteroscopy into practice, and this really came with a paper that was published by Frank Laufer where he showed that if you added hysteroscopy to your D&C, you could almost double the sensitivity of being able to pick up pathology. That was incredible.

What we now know through other studies, if you take a group of women who have a known cancer, known endometrial cancer, and you do a blind endometrial biopsy and then you do the hysteroscopy and you look at the pathology report, that really misses the diagnosis in about a third of those patients, and we know they have cancer. And if you look at a blind biopsy, it's really only effective when you have global pathology in over 50% of the surface area of your uterus. That's led ACOG to say in their most recent committee opinion for evaluation of abnormal uterine bleeding that the overall diagnostic accuracy in diagnosing endometrial cancer is very good when you get an adequate sample and when the endometrial process is global, but if you look at blind biopsies with a Pipelle, it really only samples about 10% of the cavity, so you're not getting a good sample, most of the time not getting a representative sample, unless you have a global pathology. Well, it turns out that global pathology only occurs in a small fraction of patients.

Now, here is an example. This is a 40-year-old patient who came to me. She had a biopsy done at an outside facility that was normal, she had an ultrasound that says normal, but she kept bleeding, so I took a look at the ultrasound. I encourage you to look at your own images. Don't just read the report. You can see the ultrasound here, and there's a little area I thought, well, that's kind of unusual. I do see some focal thickening there, so let's take a look at this ultrasound, and with this focal abnormality, let's just take a look by hysteroscopy and see what we see, and there it is. I see a little focal lesion down there that was totally missed by the biopsy. I take this

person to the operating room, I do a resection of this, and it turned out to be atypical hyperplasia, so we saved this patient a hysterectomy. She wanted to preserve fertility, put in a Mirena IUD, and she's doing fine. This is an example of how you can incorporate these concepts into your practice.

So, it turns out abnormal bleeding is actually very common. About a third of women of reproductive age are going to experience abnormal bleeding, but it actually accounts for up to two-thirds of the visits that any given gynecologist is going to get, particularly consults. That's pretty accurate. A lot of what I see is related to abnormal bleeding.

Now, we know there are 2 different categories of issues that cause abnormal bleeding. This is the so-called PALM-COEIN classification system of FIGO introduced by Mac Munro a number of years ago, and this breaks it down into structural abnormalities, which you can see on screen left, and nonstructural abnormalities or systemic problems that you see on the right, , your first triage is to determine which category this problem falls into. Some of those are minimal to operative intervention, and some of them are not, and so your goal here is to determine, of the majority of those that do not have a structural abnormality, how to identify the ones that do and making a decision which one of these do I need to take to the operating room? Right? That's the goal. You want to get the answer to that question. So, that's where hysteroscopy comes in. There are actually plenty of indications for hysteroscopy, whether it's an infertility evaluation, evaluation of abnormal bleeding, suspicion for uterine anomalies. Truly, there are only a few contraindications: pregnancy, known malignancy, and that's a relative contraindication, because we do know that if you do a hysteroscopy in someone who does have endometrial cancer, that does not affect their stage or grade, so it's not going to affect their outcome at all—and, of course, active infection. You don't want to do a hysteroscopy if someone has an active infection.

I like to break down the application of hysteroscopy into 3 categories. Let's take a look at diagnostic first. You can do this with or without a biopsy. So, here is kind of a plethora of different kinds of problems that you might see that are anatomic. From screen left going across, we have uterine septum, we have adenomyosis, we have intrauterine adhesions, a submucosal fibroid, endometrial hyperplasia, a polyp, and a C-section scar. These are common causes of abnormal bleeding that can be diagnosed with a quick look. And our goal is: Does this patient need to go to the operating room? That's the question that you want to ask. Is this something I can treat medically, or is this going to require surgical intervention?

Now, let's talk a little bit about polyps as a source of bleeding because polyps are actually fairly common and controversial. Do you really need to do anything about polyps? Well, it turns out that they are not really that common, maybe about 10% or so of patients with abnormal uterine bleeding but they are associated with an increased risk of malignancy, particularly in patients who have abnormal active uterine bleeding and a polyp is a source of that bleeding and in menopausal patients that have a polyp that's persistent over 1 cm in size. If you look at the actual incidence in postmenopausal women or in women with active bleeding and polyps, it's about 4%; as opposed to someone who's of reproductive age, it's really a low percentage of malignancy or neoplasia, but it can still be a source of bleeding.

Now, a little tip that I want to give you is, remember, I told you that you need to look at your ultrasounds. If you have a patient who comes in and there's a disconnect between what you see on your ultrasound and what you've got on your biopsy, if the postmenopausal patient comes to see you, she has an ultrasound that shows a 12 mm endometrial complex, you do a biopsy and that biopsy says atrophic endometrium, that doesn't match. Most of the time that's going to be a polyp, because that Pipelle biopsy is getting in there, you're sampling the uterine wall, but that polyp is flopping around and you're not getting a sample of that. You may, if you're lucky, getting a little fragment of a polyp, but most of the time not.

Another advantage of taking a look and making this triage diagnosis is that you can really make a determination of those patients that do not need operative management. This is a group of patients who came in for abnormal uterine bleeding, and you can see the table on the left, the cost of care of those patients who ended up going to the operating room, and in this study they found that over 60% of the patients that came in for bleeding actually did not need to go to the operating room for a hysteroscopy D&C. The hysteroscopy in the office saved 60% of those patients a trip to the operating room, which is a total of about \$3,500 in savings per patient. Now, that's important in a value-based system where you're being measured for your outcomes and not for your billing because you're saving the healthcare system that much money on each of these patients.

Let's turn to preparation for procedures. I do not like surprises in the operating room. I like to know what I'm getting into before I go to the operating room, and a quick look in the office will tell us. This patient on the left was sent to me because she had a big fibroid and she wanted an endometrial ablation. What I showed is that by turning the fluid up and down, this fibroid would basically disappear, so it really wasn't intracavitary fibroid. It was an intramural fibroid, and this did not obstruct her cavity. We were able to do an endometrial ablation in that patient, and you can see the result there in the first column in the middle. A patient comes to me, has a diagnosis of a septum, and that picture in the upper right corner—and I did her office hysteroscopy—I found, "Oh look, she's got a submucosal fibroid at the same time. I need to be prepared to take care of that." If I had gone into the operating room just to take care of a septum, I wasn't

prepared and I had not counseled her about a myomectomy, I haven't really helped her fertility chances at this point, so I don't like that surprise. And you can see these fibroids down here at the lower right, these are fibroids that are not going to be amenable to hysteroscopic resection. I need to tell that patient she doesn't need a hysteroscopy. She needs a bigger operation if fertility is really her concern.

There's a scale, and I encourage everyone to look up this reference and this is what I use. It's called a Step Assessment, and it looks at a variety of different components of fibroids—where it's located, how big it is, what sort of penetration there is, etc. And you come up with a score, and you can add that score up, and basically, what this is going to allow you to do is determine... And I don't care whether this is a polyp or a fibroid. This is critically important. Is this a problem I can solve? Do I feel like this is within my wheelhouse of experience? Do I need to send this to someone else who has more experience? Or, is this someone who doesn't need a hysteroscopic procedure at all? This is someone who needs a laparotomy or laparoscopy procedure instead, or maybe no procedure instead.

Now, I don't care whether you're doing a hysteroscopic morcellation or whether you're doing a loop resection. This is going to allow you to make an assessment. And that triage is critical. Know where your limits and your experience is. Can you do this? Do you need to refer this patient? Does this patient need a different operation? Being in the operating room and getting this information for the first time is not what you want to do. You don't want to put a patient to sleep and then suddenly find out, "I wasn't prepared for this. This is not a patient I'm comfortable with." Now I've got to wake her up and say, "I'm going to send you to someone else." She is not going to be happy.

Let's talk about performance of procedures and confirmation of that performance. The big things that we do in the office—hysteroscopic sterilizations, endometrial ablations—obviously doing hysteroscopy is an interval component of this. This picture on the left is a paper I published a number of years ago where we had patients who had a Mirena IUD, they were transitioning from interval contraception to permanent sterilization, and we show that you can just put that hysteroscopic sterilization procedure in without taking the Mirena out. And then, of course, endometrial ablations. So, hysteroscopy gives you a good option to guide those procedures as well as to confirm that you've done those procedures correctly.

Now, what's the problem with hysteroscopy? Historically, it has required a lot of stuff, expensive stuff, expensive toys, and if you are in private practice, this is a little bit daunting. Over the years, pioneers like Jay Cooper, Phil Brooks, Linda Bradley, Stefano Bettocchi and Keith Isaacson, you see here, have really pioneered reinvention of a lot of these tools, miniaturizing them, making them smaller, things that you can do in the office. In fact, most modern flexible hysteroscopes are only the size of things that you already are putting into the uterus every day: a sound, a Pipelle, a Mirena. It's not that much bigger. It's just all the stuff you have to do associated with it. Only about a fifth of gynecologists are actually using hysteroscopy in their office, not a lot of people really using it in the office. So, why? I break this down into 3 categories. First, what I call technophobia—people just don't understand the technology and they just don't want to go there. Just all this stuff you have to do and keep up with, it's just daunting. Number two, I call it organophobia. How do I push the buttons? How do I keep it clean? How do I do my certification? What about the room I have to have? Do I have to train my nurses? You know, all this stuff like that, it's just too much. It's not worth it. And the last one is econophobia. It's just not going to pay off. All this outlay, I'm never going to get return on my investment. Truth is the biggest problem is just overcoming inertia.

Now, let's talk about kind of bringing this into the modern world. Kathy Sierra and Dan Russell come from the video game industry, and they have a website that they call The Passionate User, and one of the things that they proposed in this website, is a predictor or a measurement of your ability to incorporate technology, and they call this the Kick Ass Curve, so I'm going to introduce you to the Kick Ass Curve. So, this looks at your ability to do something. Do you struggle? Are you fluid with it? And how long over time does that take? There are 2 landmark positions here. The first one is: How long does it take before I actually become comfortable and I'm no longer hating doing this? And they call this the No Suck Threshold. And then the next landmark is: At what point do I really become competent—I'm really hitting my stride? And this is called The Passion Threshold. And there's a predictable curve of how long it's going to take with any new technology. And Malcolm Gladwell will have you believe that that's 10,000 hours, but the truth is, it's not. He was talking about how to become a true phenom in doing something, not just being competent.

So, how do we move that curve? What if I told you that there are things that can take that curve and shift them to the left? We call those enabling technology. So, what is the enabling technology that's going to get you in your office taking care of patients with hysteroscopy? It's getting rid of all the stuff, making it economical and making it convenient. There are a couple of products that are out on the market today, and I'm going to talk to you about 2, and the reason I'm talking to you about these 2 is because these are the ones that are FDA-approved. There are more coming down the line. I don't have any relationship with either of these companies. Prometheus is a company that is a WiFi-enabled device. It's a camera that you put on to your existing hysteroscope. It then transmits these images to your laptop in a HIPAA-compliant proprietary software package, and you can get beautiful images because you can use your high-quality hysteroscope. The downside is you still have to buy a hysteroscope and you still have the cost associated with maintaining that hysteroscope, so your savings are not necessarily as good, but it's certainly a lot easier than all that cumbersome stuff we saw before.

Another one is by Cooper, the Endosee, and this one is actually reposabe. The handpiece on the left you use over and over again. The catheter on the right is replaceable and disposable, a little LED light on the end and a chip camera that transmit information to the handpiece, and you can download those later into your computer.

This is a realtime video of my fellow doing an Endosee hysteroscopy in the office. This is just a regular exam room. This is not a procedure room. We're using a 1,000 cc bag of saline or a pressure bag just because we didn't have enough nurses. You can see this whole thing took about 30 seconds, maybe a minute to do. I keep these catheters in the drawers in my exam rooms, and I keep the handpiece in my coat pocket. I'm very fortunate that I have this big setup in my office because it's a university and I didn't have to buy it, and so if I know the patient's coming in for a hysteroscopy, I'll probably use that because I'm going to be doing some sort of procedure, but for the patient who drives 3 hours to see me for postmenopausal bleeding and I'd really like to take a look inside, this is the patient that this Endosee is there for. I can save her another trip, and I can get an answer right now.

Let's talk about the economics of hysteroscopy. Whenever you do a procedure, there are 2 components to the reimbursement for that. One component is your fee for doing it, and another component is the amount of fee that goes to the facility where you had that procedure done for providing all the stuff, the staff, etc. ? And so where the money goes is you're going to get surgical compensation for doing that, and you're going to get that surgical compensation no matter where you do it. It's going to be the same. And the facility is going to get compensation. But if you do this in your office and you code this as being done in an office, CMS has provided a mechanism for the insurance companies to know that they are not going to have to pay that facility fee, and so they will channel a little bit of extra money to you for providing that place and the stuff, and that's called a non-facility fee, and so you get an added RVU, an added check for doing that particular procedure in your office.

Now, here's an example of that. This comes from the Medicaid-Medicare-CMS website for 2017, and you can see the MD reimbursement for hysteroscopy, diagnostic, surgical biopsy, etc. These are common things that you might do in the office. If you do this in an ambulatory surgery center, that's the suggested reimbursement that you're going to get. If you do this in your office, you can see that there is added RVU and added reimbursement for doing that because they are reimbursing you for the disposables, the time, etc. What you need to know is what is the difference between my reimbursement for doing it in the office versus doing it in the hospital, and you can see there on the right side that added differential, the margin, the extra money that you get, and if that covers your cost, it's worthwhile doing it in the office. ? And you can see hysteroscopy with a biopsy got a really big boost this year, so hysteroscopy with biopsy, very well-reimbursed now. This also does not take into consideration the money you're going to save because you don't have to process your equipment, you don't have to be out of your office, so you can continue to see patients in the interim and you can overlap all of your time efficiently, and not having to go back and forth between the facility and your office.

So, in summary, if you look at office hysteroscopy, it's a no-brainer. It is easy to perform, and it's well tolerated; it ensures diagnostic accuracy; it allows you to figure out what are those patients who are going to need further operative intervention versus those that I can treat in the office; it's convenient; it's evidence-based; and it is well-reimbursed even in a value-based system.

And now I want to introduce you to Ethan Goldstein, who's going to come up here and talk to you about: Okay, this all sounds fine and good, but how do I really incorporate this into my practice? How do I make this happen on a daily basis? And he's got some great advice and some great tips to show you how to do that.

(Applause)

Narrator:

If you're just joining us, this is CME on ReachMD. Next up, Dr. Goldstein will review how you can implement hysteroscopy in the office setting.

Dr. Goldstein:

I think we all walked away from this understanding the value of direct visualization for diagnosing our patients with AUB, basically, my next step is to explain how we can use this technology that we have now in single-use, disposable, reposabe technology, along with the evidence that Dr. Anderson so eloquently explained to us, to make our diagnosis of AUB with a reposabe system like Endosee point of care. And this is really a paradigm change for us, because if you walk into your primary care office with a head cold or upper respiratory infection, you know full well that you're going to have an otoscope in your ear, someone looking down your nose and your throat, and that's appropriate standard of care. So, I would challenge us to say, "Well, why not for our patients with AUB apply this similar technology for them to be able to offer a point of care approach?" I talk about Endosee mostly from Cooper Surgical because right now it is currently the only FDA-approved, single-use, disposable device or reposabe device. It has a handpiece that's reusable, like Dr. Anderson mentioned, and then the disposable cannula, which is 4 mm, semi-rigid with a 25-degree angle that houses the light source

and the camera.

This has really been a game-changer for us in our practices, because while hysteroscopy still has value and is never going anywhere, for the more complicated cases and for our resections or our intracavitary morcellation, Endosee or single-use hysteroscopy is allowing us to simplify that process, moving it into the office easier, like Dr. Anderson was pointing out, for those technophobes, the econophobes and for simplifying this whole process to make it point of care.

Before single-use hysteroscopy, my diagnostic algorithm for AUB is probably similar to most of you. I have 2 offices in Southeastern Michigan. I have an ultrasound tech 2 days a week, so I don't have the ability to use ultrasound frequently or every time I'm working up patients. I have a patient that will come in and present with abnormal uterine bleeding, do the appropriate history and physical exam. If I had ultrasound available that day, I would try to obtain that. If there was something on the ultrasound that suggested intracavitary pathology, bring them back again for a saline sonogram, another visit. Maybe most of you can understand what this is like in terms of scheduling and the inefficiency that surrounds that. Our sonographer would do another ultrasound, and she would be then waiting for me to come in and do the saline sonogram. That was just an efficiency issue for us, something that I hope never to have to do again, and with single-use hysteroscopy, I don't plan to. Then, because I don't often have time to sit down right then and there right after that procedure and explain everything and plan the next step, have them come back again, so you're looking at, for an AUB patient, 2 to 3 office visits before incorporating single-use hysteroscopy. We already know because Dr. Anderson did such a great job explaining the deficiency of blind biopsy for evaluation of abnormal bleeding. We know that seeing is believing, and so now we need to incorporate this earlier in our diagnostic workup.

This reminds me of what I think patients may go home and talk about what happened in the doctor's office, and I imagine this patient here who came in and saw this saline sonogram... I can imagine the conversation. "Well, yeah, the doctor showed me this picture of a gray blob with another gray blob inside of it and said this was the problem and we needed to go ahead and take it out," versus the patient on the other side coming in and saying, "Gosh, it was amazing. Within about 10 or 15 minutes, the doctor explained to me a way we could take a look inside and understand exactly what's going on and showed me this really cool picture of a polyp. Patients can relate to what you're showing them, so the patient satisfaction element of being able to show our patients right then and there in the office is really, really powerful. A picture really does say a thousand words in this case.

Now you look at what my algorithm is like for AUB, and you might look at this and think, "Oh my gosh, that's a lot at one visit." You're right, it is. And much like you, I'm a busy general OB/GYN. I see 30 to 40 patients a day. This is not where I'm spending all my time, okay? This is an evolving process, and that's why you see it keep moving up there. Patients come in with abnormal uterine bleeding. We do the history and physical. I ask them, "Mrs. Jones, do you have time today for a few extra minutes? By the time you leave, I promise you we can diagnose what's going on." "Do you have to go back to work?" whatever it is, "Give me another 15, 20 minutes, and we can have an answer for you." And if they can, then I keep moving. I'll step out of the room. The nurse comes in, gets a consent, gets everything set up. I'll go see a couple extra patients, come back in, do the Endosee procedure. It takes about 5 minutes. Have the patient get dressed, keep moving, go back out, see some more patients, come back in and sit down and show them exactly what's going on and at that exact visit plan the next step. Basically, single-use hysteroscopy for me is just an extension of my physical exam, and it's very, very powerful, even though only 20% of the time are you going to see intracavitary pathology—and that's great for what we talked about with Dr. Anderson in terms of preoperative planning, knowing exactly what you need, what instrumentation you're going to need for your procedures, saves me about 5 or 10 minutes in the OR every time as opposed to saying, "Oh, okay, please set up the AX\* 25:23 morcellator," or the loop or whatever you want. You know going in what you're going to deal with. The value of finding nothing, like in the patient I saw yesterday who's on tamoxifen who came in freaked out that she was having vaginal bleeding, going ahead and doing the Endosee and showing her a completely atrophic endometrial cavity, walking away so relieved that everything was okay. So, it's just part of the physical exam. Single-use hysteroscopy can be part of our physical exam and point of care.

this speaks to a little bit of a technical change. When I was in residency, we learned hysteroscopy, go up to the fundus and then work our way back. With single-use systems, I think sometimes it's easier to start lower in the lower uterine segment to get a global picture and then direct your visualization depending on what you see.

This was a 31-year-old patient who came with intermenstrual bleeding, if I did it traditionally on the left going up to the fundus, you see this little baby polyp and you're like, "Oh, that's it," but when you pull the camera back and you see what's behind, the bigger polyp what was causing the issue, it just really hit home the point that global perspective with these systems is really, really effective.

This is the same patient a couple months later to show you how clear and how easily and how quickly we can get the visual diagnosis for our patients in the office.

A 27-year-old had been having intermenstrual bleeding for several months, had been put on birth control pill after birth control after birth



control pill. We did an ultrasound one day after about 3 or 4 days after her period, showed a thickened lining. I said, "Listen, do you have a second? Let's just take a quick look." And sure enough she had a polyp that would not have been seen otherwise, so we just saved this patient more months of switching her birth control or trying other options by diagnosing right away point of care that day. Again, that's a very satisfied patient.

This was a really interesting case, 21-year-old, 2 months after having a baby, really was excited about having more kids in the near future, didn't want to go on birth control, had stopped bleeding after about 6 or 7 weeks but then began bleeding irregularly and abnormally at that point. And we all know what that's like when we see our patients and something just doesn't seem right. I said, "Do you have a few minutes? Let's take a quick look." And sure enough she had retained products, as you can see here, saved her a ton of visits.

So, what about the lost IUD? We all struggle with a lost IUD. I'll show you a video in a minute of removing an IUD with a single-use hysteroscopy unit, the Endosee unit. Pre and post ablation, like Dr. Anderson also mentioned, instead of having the bag of fluid set up, I don't use a big liter or 3 liter bag of fluid. I use a 60 cc syringe and some extension tubing.

What about looking for adenomyosis, which we can pick up on MRI, and pick up on ultrasound. We can also see it hysteroscopically, and that may very well guide your counseling for the patient regarding hormonal therapy versus ablation versus hysterectomy.

And uterine anomalies for our patients with recurrent miscarriages.

Here is that video I was talking about of a retrieval using a micro grasper right alongside the 4 mm cannula of the Endosee. This took about a minute, and the patient walked out the door happy as could be that we were able to get her IUD out. So, even though it doesn't have an operative channel at this point, this system is really effective for performing procedures such as that.

Another patient of mine, postmenopausal patient, just to show you, just again, clarity and effectiveness of this technology for diagnosing, she had a uterine synechiae, and she also had cervical stenosis, which with a 4 mm instrument is very, very easy to overcome.

This is another postmenopausal patient who was on HRT for 5 years, came in with abnormal bleeding and a thickened lining on ultrasound. Obviously, we have to wait until we have formal pathology, but the gross examination of what we could see looked pretty benign like a benign polyp, and she was a very satisfied patient as well.

So, my procedure, because I have that kind of keep moving mentality, that patient gets 600 or 800 mg of Motrin to start with. I would do a bimanual examination. I use a lighted speculum, Betadine prep, tenaculum if I need to, and most of the time I do because it does facilitate this procedure. If I have to dilate, it's not very much. We're talking about a 4 mm instrument. And then go ahead and proceed. I think the reason why I like to show this picture is that, unlike the video Dr. Anderson showed, I like to put the cannula in first. We're all used to this procedure. We're all used to this movement with an endometrial sound, with putting in an IUD, with doing a biopsy, so it's no different. If you have the camera hanging on the end, it's a little bit cumbersome, so I insert the cannula just into the lower uterine segment and then go ahead and attach the handpiece, and I find that to be very effective.

So, in summary, my hope was to take all the information we learned from Dr. Anderson that's compelling that shows us that really seeing is believing, that the direct visualization of our patients with AUB is vital and important and valuable, and combining that with the technology we have with single-use hysteroscopy systems like Endosee, to make this a procedure that we can do any room at any time; we can do it quickly without interfering with the flow of our busy practices, causing little or no pain or discomfort, saving the system money like we saw, also a revenue point for us, which is also nice. We have something that benefits the patient, the practice, and us. And at the end of the day, we have a satisfied patient. They walk out the door knowing exactly what's going on. Do we have to plan something procedurally? Do we have to get some laboratories, talk about hormonal evaluation and management? They know right then and there what's going on.

Thank you very much.

Narrator:

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