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Improving Severe Asthma Outcomes: A New Era in Identification and Management

Announcer:

Welcome to CME on ReachMD. This activity, entitled “Improving Severe Asthma Outcomes: A New Era in Identification and Management” is jointly provided by the University of Cincinnati and CORE Medical and is supported by an independent educational grant from Genentech, Inc. and AstraZeneca.

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Dr. Russell:

Many patients with asthma are managed by their primary care providers. Severe asthma in particular has been linked to significant morbidity, healthcare resource utilization, and long-term sequelae, such as airway remodeling and a greater risk of developing COPD. These consequences emphasize the importance of improved identification and management. An increased understanding of pathophysiology and its correlation to disease activity have identified key therapeutic targets. Biologic therapies that target T2 pathways and new supportive digital health technologies mark a new era in asthma management.

Coming to you from the ReachMD studios in Fort Washington, Pennsylvania, this is CME on Reach MD. I'm Dr. John Russell. Joining me to discuss how we can optimize outcomes in severe asthma is Dr. Barbara Yawn. Dr. Yawn is adjunct professor in the Department of Family and Community Health at the University of Minnesota. She's also chief medical officer for the COPD Foundation.

Dr. Yawn, welcome to the program.

Dr. Yawn:

Thank you for having me.

Dr. Russell:

So, starting out today, Dr. Yawn, as an expert in both primary care and lung diseases, looking at the big picture of asthma, how would you describe the state of asthma management in today's practice, and what is your aspirational hope that it will become?

Dr. Yawn:

Well, asthma management is actually better than it was, say, 10 or 15 years ago. We have more people that have recognized the value of guidelines and guidance and tools, and they're being used more often, and so I am actually pleased—we'll talk about the aspirations in a minute—but I am pleased that it seems to be moving forward. We still have some ways to go. For example, people don't always make the diagnosis of asthma as quickly in a patient's disease state as I would like them to. I think we need to think about people, who have current episodes of respiratory illnesses and think, “Gee, is this something more than just a whole bunch of acute episodes? Is there something chronic going on?”—so continuing to think about the diagnosis of asthma; once we make it, making sure we assess the severity of the asthma so we can start therapy based on that severity; and then doing follow-up. I think that's one of the areas we still have a long way to go in primary care. We would never take care of a person with diabetes without having them come back every 3 to 6 months, but we take care of people with asthma and say, “Well, come back whenever you need to.” No, we need to have them also come back on a regular basis so we can assess how are they doing? How is their control? And if the control is not good, then we figure

out—well, why is it not good? Is it triggers? Is it adherence? is it poor inhaler technique? is there something else going on? Are they depressed and they're just not taking their medicine?—so, following, monitoring, assessing control, thinking about next steps.

And there are several tools now that most of us know about that are good for assessing control. The ACT, the Asthma Control Test, is one of them. The lower the score is, the worse the control. It's a pretty simple, straightforward 5, 6 questions. I think it's great for specialists, but in primary care I think we might need a little more. And actually, I've helped develop another one called the Asthma APGAR, and it talks about the level of symptoms in the daytime, nighttime, and changed activities, but it also asks about what makes your asthma worse, it asks about triggers, because we frequently in primary care forget to ask about those very important things that make a huge difference. It also goes on to ask about—how do you take your medicines? Why do you take them? Why do you not take them?—because a lot of people don't take their asthma medicines. They don't know how, we haven't done a good job of explaining it, or they are fearful. The other thing that I like about the Asthma APGAR is it is linked to a care algorithm so that you don't say, "Oops, they're out of control. Let's add another drug." Well, maybe that's not the best step, and the Asthma APGAR and the algorithm helps.

And one of the things that I would really love to see us use more and more is an Asthma Action Plan. I think we're recognizing in this COVID era that patients take care of themselves at home a lot of the time, most of the time in fact. And so having an action plan really helps support a patient knowing what to do. What do I do when my symptoms are worse? What do I look for? What should be my action? When should I call my doctor's office? When should I go to the hospital? All of those things are very helpful, and so those are some of the kinds of things that I hope we incorporate more and more into our asthma management.

Dr. Russell:

So, Dr. Yawn, as a follow-up to what you just talked about—you certainly used the word control a lot—so, in our primary care offices, when you have that person who's uncontrolled, how do you approach that patient?

Dr. Yawn:

I think you have to think about why are they uncontrolled. And again, I emphasize they're probably not usually uncontrolled just because it's a lack of a medication. Now, it is in some cases but not in all cases. So, what are the possible areas that we should think about? One is indeed the disease state, and maybe they do have more severe disease than what we're currently treating, but that's only one. There are a whole lot of patient factors, and I mentioned some of them: adherence, poor inhaler technique, misunderstanding, thinking that "Gee, I don't have any symptoms today, so my asthma went away; I don't need my medication." There are physician and healthcare professional factors. We haven't done a good job of explaining to the patients what they need to do. We haven't followed up on adherence and asked why maybe they're not adhering. We may not have helped them stop smoking. So, those are some of the factors we have. And then, of course, there are environmental factors we need to think about, such as: are they living in a house where somebody else is smoking if they're not smoking? Are they in a house with a pet that they're allergic to? Have we assessed their allergies? Are they in an environment that has very heavy air pollution? So, all of those factors need to be taken into account.

Now, when we talk about the patient factors and disease factors, we sometimes think about the phenotypes and the endotypes and how they may play into lack of control. Phenotypes are the characteristics of the patient, and the endotypes are more the disease characteristics. With the phenotypes, we might talk about: well, is it allergic asthma? Is the patient overweight and this has to do with obesity? Are they allergic to aspirin and that brings on the asthma attacks? When we think about then going on to the endotypes, we do have some metrics now that we can use, like serum eosinophilia, and that's pretty easy to get. We can use IgE. The general IgE or total IgE isn't very helpful, but we have specific IgEs against certain allergens like cockroaches or oak trees or ragweed or whatever it is that can really help us. And then there are things that we don't use very often in primary care, like exhaled nitric oxide or FeNO. Those can all help define the patient's asthma a little better and help us decide why they might not be controlled.

Dr. Russell:

So, doctor, thinking about severe asthma... So, uncontrolled asthma, is that a continuum to severe asthma? Are they separate things? It would be great if you could help us define what severe asthma is. Is it an aberration, or is it something that's walking into our office every week?

Dr. Yawn:

Well, severe asthma is walking into our office every week, and we may not be always paying attention. Now, it isn't everybody with asthma. Severe asthma and uncontrolled, as you suggested, really can overlap. There are people that have uncontrolled asthma because they never take their asthma medications, and we don't know if they are severe or not because severe asthma is actually defined as someone whose asthma is not controlled—and we only talk about in 6-year-olds and older for the moment anyway—so a 6-year-old or older person with asthma whose symptoms are not controlled, with moderate to high-dose inhaled corticosteroids plus either a bronchodilator or a leukotriene modifier. If they are on those and their symptoms are still not controlled or if they are using oral

steroids 50% of the year or more, these are the people that are called severe asthma.

We need to think about the people that are uncontrolled because that's the first thing we're going to have is the uncontrolled, then decide are they uncontrolled despite this very appropriate pharmacotherapy and smoking cessation and other things. If they still are uncontrolled, then this is severe asthma. And uncontrolled is probably about 20% of our patients, but severe asthma in a primary care practice is usually somewhere between 3–5% of our patients, so we do have them. That's about 1 out of every 20 people we see with asthma probably has severe asthma, and we want to continue remembering if you've gone up the step therapy and you're all the way at step 4 or 5, depending on whose guidelines you're using, but you're at the step where you're on inhaled corticosteroid daily, medium- or high-dose, you've added the bronchodilator, you've added the leukotriene modifier and they're still having trouble or they're having multiple exacerbations or attacks where you're using corticosteroids, oral corticosteroids very frequently, this is severe asthma.

Dr. Russell:

So, for these 3–5% of patients with asthma who are walking in our office, what do you think the role of our colleagues in pulmonary medicine, our colleagues in allergy and immunology... do you really think it takes a village to care for people with severe asthma?

Dr. Yawn:

Oh, it does. It absolutely does. I think that my role is first to make sure that I believe they have asthma, that I have tried the appropriate therapy, that I have followed them up. I would make sure they're adhering. I try to make sure they have good inhaler technique. I try to keep them from the triggers. But if I've done all of those things or if I'm not very comfortable with the diagnosis and say, "You know, this just doesn't make sense, it's just not quite what I'm comfortable with," then I'm going to refer them to either my allergy or pulmonology colleagues. And they're going to do some of the same steps. They're going to make sure that the patient actually has asthma and it's not something else that's masquerading as asthma, like vocal cord dysfunction, for example. They are then going to look at what we've done for therapy and decide have we done all the appropriate things or did I miss a step somewhere. And if I have done all the things that we know how to do, they're then going to consider whether or not there are other therapies that I usually don't start, and right now those are the biologics, the monoclonal antibody therapies that have been on the market. One of them has been on the market for 20 years, but several of them are new within the last several years. And I really like my specialty colleagues to help me decide that a patient is a candidate for one of these.

Dr. Russell:

So, Dr. Yawn, kind of pivoting to what you just talked about in the management of those patients with severe asthma, what are the therapies you think that we should be using in concert with some of our specialty colleagues and what type of biologics? Could you expand a little bit further on what biologics are available for our patients?

Dr. Yawn:

Yes. Biologics, as I said, are monoclonal antibodies, and they are really kind of exciting because, as you know, usually steroids have been the basis of our asthma therapy, and steroids are like just turning on a fire hose. You just kind of shoot everything that's in front of you with the fire hose instead of trying something that's more focused. The biologics are actually more focused on certain parts of the inflammatory cascade that we all remember from way back in medical school, but the biologics are on certain parts of that inflammatory cascade.

Currently, there are 5 of the biologics that are approved by the FDA. So, let me just quickly go through each one a little bit. Omalizumab, is an anti-IgE. It's approved for people older than 6 who have allergic asthma and are inadequately controlled with high-dose ICS. We used to do it as an injection weekly, and we have now realized you can move it out, and frequently people are getting injections only every 4 weeks or so. And then there are 3 that are IL-5 either antagonists or receptor antagonists, and that's mepolizumab, reslizumab and benralizumab. And then there is one that is an IL-4 receptor antagonist, also works on IL-13, and that's dupilumab.

So, of the IL-5s, we have mepolizumab, which is a subcutaneous drug that is appropriate for 6 years and older and people that have severe eosinophilic asthma. It's given subcutaneously. It is approved for home administration after you initially start it in the specialist's office. The patient may be taught and then do it at home. It has about a 53% reduction in exacerbation rate over the first year. The next of the IL-5s is reslizumab, and it is for patients 18 or over, and it's actually an IV infusion, so usually it's given when the patient goes to an infusion center. It is for severe eosinophilic asthma also, and it has about a 50–60% reduction in exacerbations. The third one is benralizumab, and that's an anti-IL-5 receptor antagonist, and it is approved for patients 12 and older with severe eosinophilic asthma. Like the first one I mentioned, the mepolizumab, it is also approved for subcutaneous administration and home self-administration. The rate of reduction for exacerbations with benralizumab is somewhere between 30% and 50% depending on the specific dose. The last one I just want to mention is the dupilumab. That's the one that's the anti-IL-4 receptor antagonist, also works on IL-13, and it's approved as maintenance add-on therapy. And I should have said that before. All of these are add-on to the other inhaled therapies.

Dupilumab is for patients 12 years and older with moderate to severe eosinophilic asthma or corticosteroid-dependent. It is subcutaneous administration, can be done at home. And one of the things that's interesting about this one is that it is also approved for severe eczema and for patients with recurrent nasal polyps, so you may, when you send them off to the specialist, find that if they also have severe eczema, that they choose dupilumab rather than one of the others. And the other thing is that if your patients go and you find that "gee, this one is not working," they really may do well changing from one of the biologics to a different kind of biologic.

Dr. Russell:

So, that being said, Dr. Yawn, as a thought leader in respiratory illnesses, there must be some other medicines that are on the horizon, correct?

Dr. Yawn:

Well, there are. There is one of the biologics that is actually in fairly late-stage phase 3 studies, and that one is a TSLP-blocking agent, which is another sort of chain or variation of the inflammatory cascade, and there are several studies going on. There's the PATHFINDER trial. There are the NAVIGATOR and the SOURCE studies. We hope that those studies will be finished and the data available within the next year to 18 months. And then, of course, we know it will take the FDA a little while to review it. So we do have new things coming up, and this new one is not so dependent on eosinophilia, so it will be interesting to see exactly which subgroup of severe asthma patients it's indicated for.

Dr. Russell:

So, in the year 2020, every type of physician has found themselves doing a level of telehealth that they never did before. And certainly, when we're caring for patients who have asthma who are going to have cough and shortness of breath, there's a reticence to bring those folks into the office, and we are more and more reliant on patient kind of self-care. Are there some digital tools to help that clinician on the phone with their patient with asthma kind of self-manage a little bit better?

Dr. Yawn:

Well, there are. There are several different kinds of tools that really, I think, can help strengthen the interaction with the patient and their family. There are tools that can help with adherence, for example. There are little devices that fit on either the MDI or even the DPI inhaler that can record every time there's an actuation of the inhaler, and they can be linked to an app that reminds you "Gee, you haven't taken your medication today, and it's an hour past the usual time," so there are reminders like that. I mean, there are the simple reminders that we all know about. I can put a reminder on my cell phone or other device, even on my Fitbit kind of thing that says "take your medicine," so those can be very helpful.

There are some new devices coming out that not only tell you whether or not the patient actuated their inhaler or whether or not it was an acceptable inhalation, and that's going to be a really good breakthrough because then we know about inhaler technique. There are also devices like Pulse Ox. Patients can have a Pulse Ox at home if they are having a lot of problems or have severe asthma. We have tools that allow the patient to record their symptoms every day, so you can get a pattern and see how the symptoms are doing over a period of time, kind of like we get a hemoglobin A1c for diabetes. We don't get just 1 day. We get a whole month or 2 months. There are several of these tools that I think are really very helpful. There are also websites and groups that patients can join. There are Better Breathers Clubs that have now become virtual that people can talk to other people with asthma; parents can talk to other parents of children with asthma.

All of these kinds of tools seem to be very helpful, and one of the ones I really like—we've talked about inhaler technique and the fact it's such a problem—there is an app. It's from the COPD Foundation, but the drugs, the medications and the inhalers are the same for asthma, and you can go and download this app for free off of Google Play, and it's just called the Patient Pocket Guide, and it has all of the inhaler technique videos on there so the patients can watch them at home, parents can watch them at home, because we need repeated support. I use them in my practice when I'm giving a patient a new kind of inhaler and I want to teach them. I have them actually watch the video with me, and then I have them show me how they think they are supposed to use their inhaler.

Dr. Russell:

So, Dr. Yawn, can you just say that app name one more time?—because I find that fascinating. The Patient Pocket Guide?

Dr. Yawn:

It's from the COPD Foundation, and it's just the Patient Pocket Guide. There is actually on that same app a health professional half of that pocket guide, and it has the same tools on it, but again, I think it's just really helpful for the inhaler videos.

Dr. Russell:

So, Dr. Yawn, we covered lots and lots of ground today. Could you summarize a couple points that you think are the most salient things that we discussed today?

Dr. Yawn:

Sure. I think we start by making sure we're treating the right diagnosis. We need to confirm that indeed this patient has asthma. And then we need to assess initially their severity but their control on an ongoing basis, which means we have to have them come back for regularly scheduled visits. Don't wait until they are ill but really come back and find out how things are going. If they are not going well and they have uncontrolled asthma, then we need to decide is this uncontrolled asthma or is it severe asthma. And if it's severe asthma, then I think that's when we really need to include our specialist colleagues for referral for them to evaluate and consider is the patient appropriate for some other type of therapy, including the biologics.

Dr. Russell:

Those are great points for us to keep in mind as we come to the end of today's program. I want to thank my guest, Dr. Barbara Yawn, for helping us better understand current and emerging therapies in severe asthma. Dr. Yawn, it was great speaking with you today.

Dr. Yawn:

Well, thank you very much. I enjoyed speaking with you.

Announcer:

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