



VOLUME 6 - ISSUE 6

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Trends in Inhaled Antibiotic Therapy

Our guest authors are Daniel Heintz, MD and Karen McCoy, MD, from the Pediatric Cystic Fibrosis Center at Nationwide Children's Hospital in Columbus, Ohio.

After participating in this activity, the participant will demonstrate the ability to:

- Determine the timing and selection of inhaled antibiotics associated with the Pseudomonas eradication protocol.
- Identify patients who need to initiate alternate monthly inhaled antibiotics.
- Summarize the inhaled antibiotic needs for the teenage patient with cystic fibrosis.

Unlabeled/Unapproved Uses

Dr. Daniel Heintz and Dr. Karen McCoy indicate they will discuss unapproved therapies currently under research, including aerosolized vancomycin, liposomal amikacin, colistimethate, and levofloxacin.

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Guest Faculty Disclosure

Dr. Daniel Heintz reports that he has no relevant relationships with any commercial entity.

Dr. Karen McCoy reports that she has received grants from Pharmaxis, Novartis, Alcresta, Vertex, Novalis, Gilead, and Pro-QR Therapeutics.

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Podcast Transcript

MR. BOB BUSKER: Welcome to this eCysticFibrosis Review Podcast.

Our guests today are from the Pediatric Cystic Fibrosis Center at Nationwide Children's in Columbus, Ohio. Dr. Karen McCoy is director of the Center, and Dr. Daniel Heintz is a fellow in Pediatric Pulmonary Medicine. Today's discussion is a follow-up to their recent newsletter issue on "Trends in Inhaled Antibiotic Therapy."

eCysticFibrosis Review is jointly presented by the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing. This program is supported by educational grants from Chiesi USA, Inc., Vertex Pharmaceuticals Incorporated, and Gilead Sciences.

Learning objectives for this audio program are that after participating in this activity, the participant will demonstrate the ability to:

- Determine the timing and selection of inhaled antibiotics associated with the *Pseudomonas* eradication protocol.
- Identify patients who need to initiate alternate monthly inhaled antibiotics.
- Summarize the inhaled antibiotic needs for the teenage patient with cystic fibrosis.

Dr. Daniel Heintz reports that he has no relevant relationships with any commercial entity.

Dr. Karen McCoy reports that she has received grants from Pharmaxis, Novartis, Alcresta, Vertex, Novalis, Gilead, and Pro-QR Therapeutics.

The faculty also report that in today's program they will discuss unapproved therapies currently under research, including aerosolized vancomycin, liposomal amikacin, colistimethate, and levofloxacin.

I'm Bob Busker, managing editor of eCysticFibrosis Review. Dr. Heintz, Dr. McCoy, thank you for joining us today.

DR. DANIEL HEINTZ: Thank you very much. It's a pleasure to be here today.

DR. KAREN MCCOY: It's a pleasure to be here, thank you.

MR. BUSKER: Your newsletter issue, doctors, presented important new findings about managing *Pseudomonas aeruginosa* infections with inhaled antibiotics. I'd like to focus today on how that information can improve patient care in the clinic. So start us off, if you would, Dr. Heintz, with a patient scenario.

DR. HEINTZ: The first case is an 8 month old infant who has typical CF and who has been thriving and doing well clinically. He's on standard therapies including a chest vest twice a day. He uses albuterol, pancreatic enzyme replacement therapy, salt replacement, and his CF vitamins. At baseline he usually has no cough, but during a routine clinic visit two weeks ago a culture grew *Pseudomonas*. It's the first time he's grown *Pseudomonas* on his cultures. We talked to the parents, who say

he has had a cough for the last 10 days. We did an infant PFT at 6 months of age, which showed that his FEV₅ is 114 percent predicted.

MR. BUSKER: So this 8 month old patient — would you start him on antibiotics immediately?

DR. HEINTZ: You could probably go a couple of ways with this case. First, he's a well child. His FEV₅ is 114 percent, which means his lung functions are doing very well, and if the parents are not too worried about this, I think the next step is to do a second culture to confirm the diagnosis of Pseudomonas. It's possible this could be just a contaminant or he has a viral infection that's growing out which is causing the cough. In those cases you might want to hold off starting antibiotics and then just do the second culture.

If the child is ill, though, or the parents are very concerned about the result, clearly you could start antibiotic, but I would probably get the second confirmatory culture prior to starting antibiotics. We're trying to do a judicious use of antibiotics. In CF we're most concerned with side effects of medication. In this patient we would start an aminoglycoside, tobramycin, which has side effects of nephrotoxicity. The side effect profile is cumulative, so after a decade of using a lot of these drugs, you're more likely to have issues with nephrotoxicity. Because of that we want to start antibiotics wisely when we think it will benefit the patient the most.

MR. BUSKER: What about attempting Pseudomonas eradication in this patient? Dr. McCoy, would you consider that?

DR. MCCOY: Certainly if we had achieved a second positive culture, eradication would be the way to go. That would be accomplished generally by using some of the available antibiotics that are approved for this use.

MR. BUSKER: The eradication protocol – would you briefly summarize that for us, please.

DR. MCCOY: We would select either an inhaled tobramycin or aztreonam and use that for 28 days, and along with that, because of the nature of Pseudomonas resistance, we would employ an oral quinolone for about 14 days. Those two would be given together at the same time, with a little longer tail of two weeks on the inhaled component.

MR. BUSKER: Attempting eradication in an 8 month old infant — are there particular issues that clinicians should be aware of?

DR. MCCOY: Compliance or adherence issues are always a consideration in chronic disease. We try to educate the parents extremely well so they understand the reason for using the drugs and for doing them exactly as described, or we employ some other things such as increased chest physiotherapy. It would always be important to realize that adherence plays an important role in this disease process.

MR. BUSKER: So despite potential adherence issues, you do believe that eradication in this infant is important.

DR. MCCOY: I absolutely do. Eradication is always to be attempted because colonization with Pseudomonas, once it becomes chronic, leads to decreased lung function over time and an increased expectation of earlier mortality. That is fairly straightforward and has been demonstrated many times.

MR. BUSKER: Determining if Pseudomonas eradication is successful — what's the process?

DR. MCCOY: We would always reculture after this treatment course, and if it regrew, we failed eradication. Or it might be that we've been very successful and it could be months to years before it regrows.

MR. BUSKER: Is there a preferred order of the interventions to maximize airway therapies? Dr. Heintz?

DR. HEINTZ: There is a preferred order. Usually we start with the medication, then move to the vest, and then finish up with any antibiotics or steroids. The first medication we usually use will be albuterol, which is a bronchodilator that helps open up those airways. This patient is already on albuterol. In older patients, which we'll talk about later, there's hypertonic saline and Pulmozyme, as well.

Hypertonic saline is useful for replenishing the ASL level in the mucous layer of the airways. By making that bigger, the airway cilia are able to move better and the mucociliary elevator is able to help rid itself of the mucus. We usually use Pulmozyme when the mucus is thick because it is a mucolytic that helps thin out and break down the mucus. You can use albuterol, hypertonic saline, and Pulmozyme either before or during the chest vest.

We start the chest vest itself very early in infancy. There are two basic types of vest. One is from Hill-Rom Vest and the other is the RespirTech InCourage. We can start the Hill-Rom at a circumference of around 19 inches around the baby, and the RespirTech at 16 inches. Both of those have counters to download information if you need to see how often they're being used. We typically don't do that very often, but that technology is there.

Finally, when the vest is completely stopped and we've used up all the albuterol, technically the airways are about as clean as we're going to get. Then we want to use an antibiotic and steroids to help with any infections or to decrease the airway inflammation.

MR. BUSKER: Thank you, doctors. And we'll return, with Drs. Daniel Heintz and Karen McCoy, in just a moment.

MR. BUSKER: This is Bob Busker; I'm the managing editor of eCysticFibrosis Review.

eCysticFibrosis Review is a combination newsletter and podcast program delivered via email to subscribers. Newsletters are published every other month. Each issue reviews the current literature in areas of importance to pulmonologists, gastroenterologists, infectious disease specialists, pediatricians, respiratory therapists, dietitians, nutritionists, nurses, and physical therapists.

Bimonthly podcasts are also available as downloadable transcripts, providing case-based scenarios to help bring that new information into practice in the clinic.

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I'd also like to tell you about the "CF Family Day Meeting Builder." This is a one stop shop to help you create patient and caregiver education and Family Day meetings. To find out more, please visit www.CFfamilyday.org.

MR. BUSKER: Welcome back to this eCysticFibrosis Review podcast. I'm Bob Busker, managing editor of the program. We've been talking about "Trends in Inhaled Antibiotic Therapy" with Dr. Karen McCoy and Dr. Daniel Heintz from the Pediatric Cystic Fibrosis Center at Nationwide Children's in Columbus, Ohio.

Our focus is on how some of the information presented in our guests' newsletter issue can be applied in the clinic. So let's continue, if you would please Dr. McCoy, with another patient scenario.

DR. MCCOY: Recently I saw an 8 year old girl with typical CF and no baseline symptoms. Her nutrition was good, her FEV₁ was near 100 percent predicted, and she's had the third consecutive culture positive for *Pseudomonas aeruginosa*. She previously had grown only methicillin-sensitive staph. Her parents are very adherent with therapies, including vest performance for 25 to 30 minutes twice a day and her usual baseline therapies along with that, and they come to clinic regularly at least every 12 weeks.

MR. BUSKER: Thank you, Dr. McCoy. We've been talking about the need to attempt Pseudomonas eradication as early as possible. And so let's assume we're going to try it in this patient. What are some of the factors can affect the success of eradication? Dr. Heintz?

DR. HEINTZ: Pseudomonas is a kind of funny bacterium in that when you initially get it, most of the time you don't have any biofilm. We call that nonmucoid, so it doesn't cover itself in this slimy layer. As you continue to get Pseudomonas, it eventually adheres to your airways and then starts developing the slimy airways. That's a way for the bacterium to protect itself because drugs or anything we want to use on them have a very hard time penetrating into that slimy layer to get to the

organisms. They will aggregate and create almost a matrix, again making it harder for any therapies to get to it. So whenever you have a mucoid Pseudomonas, your ability to effect change in the airways is greatly compromised.

The slime layer has a negative charge, and a lot of the medicines that we use also have a negative charge, so they repel each other and the medications can't penetrate. We need some sort of neutral antibiotic that can penetrate through that layer and affect the organism, and those therapies are currently under study.

MR. BUSKER: Dr. McCoy, what can you do if eradication just is not possible — you simply are unable to achieve it?

DR. MCCOY: In that case we would explain the situation to the parents and offer them the opportunity to start alternating tobramycin or aztreonam every other month as an inhaled medicine to see if we can control the Pseudomonas, even if we can't eradicate it. Other options are to temporarily increase chest physiotherapy, the vest in this case, but while it's never wrong to temporarily increase, nonadherence or noncompliance is associated with asking something the patient can't do. Later we could discuss whether to add dornase or hypertonic saline if we used our other approaches and feel that the patient needs a little more help to be able to help move out the mucus.

MR. BUSKER: Is there any particular age barrier to adding a dornase or a hypertonic saline?

DR. MCCOY: Not really. We can go fairly low in age if we need to. But again, we don't want to overwhelm the patient and the family by adding some of the most onerous therapies we do. The inhaled therapies take time and attention and cleaning, so we try not to overwhelm them by trying everything at once.

MR. BUSKER: Thank you for that case and discussion, doctors. Let's move on to another patient scenario. So if you would Dr. Heintz.

DR. HEINTZ: Our last case is a 14 year old girl who is chronically colonized with Pseudomonas. She's a cross-country runner and her BMI is currently in the 10th percentile. She claims to be adherent to her vest, but she doesn't do so well with the Huff cough clearance. Her lung functions have been ranging in the 68 to 75 percent predicted range, and two feed tubes are available for her weight, though she uses those inconsistently. Her CPT consists of nebulized tobramycin on On months, and on Off months she uses Pulmozyme, hypertonic saline, and occasionally intermittent additional oral antibiotics. Despite saying that she's been doing well, she's required admissions for IV antibiotics four to five times in the past two years. Usually those admissions occur when she's on the Off cycle from her nebulized tobramycin. Her FEV₁ has also continued to decline despite her frequent admissions for IV antibiotics.

MR. BUSKER: She's spending a lot of time in the hospital, and those exacerbations are happening during the months she's off the inhaled tobramycin. What are the available options to better treat this patient?

DR. HEINTZ: At this point we could try several options. The first would be to start increasing her vest therapy. I would do that as a temporary measure, not as a permanent therapy. Usually the chest vest takes 20 minutes each time, so doing it twice a day already takes 40 minutes. You can imagine they're at least taking an hour to complete both of those. Adding another therapy on top of that takes up a lot of their time, and that's pretty important, especially for a teenager who is always on the run. In that kind of case you might want to try a handheld CPT such as an Acapella. It still takes 20 minutes to do, but it's portable and can be used in other places, whereas the vest is rather bulky and can only be done at home.

The other consideration I would probably do is work with her Huff cough. It's for the patient to be able to do this because it brings the mucus up out of the airways. There is a special technique that's almost like wheezing. The patient tries to get everything out through a wheeze, which sets up a vibration that forces the mucus out. So improving that will probably help her out a lot.

You could also accept this as her new baseline perhaps. If you've tried a lot of things without budging the FEV₁, beyond the predicted, this just may be her new baseline — but we hate to admit to that.

The last thing we would probably do is adding another inhaled antibiotic to her Off month, because her admissions seem to be in conjunction with these Off months. By adding another antibiotic you may help keep her away from hospital admissions. I think adding aztreonam would be a good choice here, because now you would have tobramycin on one

month and alternate that with aztreonam so she's constantly covered. The only problem with aztreonam is that it's now three times a day instead of twice a day, so even though it takes two minutes to perform, the cleaning involved with the equipment takes just as long as if you were just doing the regular chest vest therapy and everything else, so it adds another burden to the patient.

MR. BUSKER: This patient is a teenager, and we know that teenagers rarely do what they're supposed to. Do you suspect she's not complying with her treatment regimen?

DR. HEINTZ: With the four to five admissions, it screams out that this patient may be nonadherent and not doing her therapy, and so by adding more things on top of something that she may or may not be already doing, your success rate may not be as great.

MR. BUSKER: Dr. McCoy? Dr. Heintz mentioned the concept of alternating or cycled therapy — tobramycin for a month and then, instead of a month off of therapy, using another inhaled agent like aztreonam in that off month. What's your experience been with that?

DR. MCCOY: We have seen mostly stabilization both of FEV₁ and need for hospitalization in that context when a patient there is clearly flaring in the periods where they don't have antibiotic protection. Dr. Heintz is completely right that the first things we ask are how are you doing your therapies, are you doing your therapies, what's the level of adherence and nutrition that supports everything else that we do.

MR. BUSKER: We've talked about tobramycin, we've talked about aztreonam — are there other inhaled antibiotics that we haven't discussed that might be considered in patients like this?

DR. MCCOY: Once we get to those antibiotics and they've both been used, we've exhausted our currently approved medications in the United States. That doesn't mean other things aren't done off label, but they *are* off label. Some people use amikacin, either as an IV drug in the hospital or as an inhaled off label drug. But these are last ditch efforts. Some people use colistimethate in an inhaled solution form that's made up from the IV preparation and has stability issues, and if we use it IV, there can be nephrotoxicity and neurological dysfunction. In Europe they are using dry powder colistimethate, which does not have any of the problems associated with the solution form that is made up from the IV preparation.

I will point out again that amikacin in that form, Colistin made up IV form, are not approved for this purpose. And the dry powder colistimethate is not yet approved in the United States, though it may be in the future.

MR. BUSKER: Dr. Heintz, your comments on additional antibiotic agents, available now or expected in the future?

DR. HEINTZ: We're limited in the classes of antibiotics we can use for inhaled antibiotics, and so we're working on trying to bring about more classes into the picture. One of these is inhaled levofloxacin. It's recently completed its phase III trials, the results aren't out yet, but the phase I and phase II studies showed it to be safe. It has improved lung function and decreased *Pseudomonas* density in the studies already performed. This would be important tool in our arsenal that we could use against *Pseudomonas*.

We also have liposomal amikacin. As I mentioned earlier that the problem with the biofilms that are produced is getting the antibiotics past the slimy layer of the biofilm; the liposomal is neutral and so it goes through that layer. It acts as a surfactant, and as it goes through the layer and reaches the *Pseudomonas*, which produces its lipoprotein and activates the antibiotics so they can start attacking from down below. Liposomal amikacin has just completed the phase II trial and the results aren't out yet, but we're anxiously awaiting those as well.

Another possibility is *colistimethate*. It's currently not approved in the United States, but it's widely used in Europe. I think as we get further studies and/or side effect profiles from this, there's a possibility that it may be approved here, but so far there has been no talk on that.

Another inhaled antibiotic, shifting away from the *Pseudomonas*, is against MRSA, and this would be important. Currently there's no consensus on how to eradicate MRSA infections in the airways, so we just use IV antibiotics. For MRSA they're coming out with an aerosolized vancomycin, which so far has been in phase II studies, and it has been shown that it's

helping decrease the density of the MRSA in the sputum. That's an interesting possibility.

For the future, a big topic is, we're using a lot of antibiotics but don't know what are the effects on the lungs. We used to think that the lungs were a sterile environment and that nothing grew in there, but within the last 10 years we've started to realize a lot of things are going on such as bacteria, viruses, and fungi that may be important for good health. Just as the skin has bacteria that enable us to stay healthy, that may be also true for the lungs. By giving antibiotics, we start changing the environment down in the lungs, which may be playing havoc with the CF patient. I think more information on the microbiome and the effects on that would be an interesting thing to watch out for.

These medications are currently under study but are not approved in the US, so we don't have access to inhaled levofloxacin or liposomal amikacin at this time, but that's what the studies are working toward.

MR. BUSKER: Dr. Heintz, Dr. McCoy, I want to thank you both for today's discussion. Let's wrap things up now by reviewing what we've talked about in light of our learning objectives. So to begin: the timing and selection of inhaled antibiotics associated with the Pseudomonas eradication protocol.

DR. HEINTZ: We don't necessarily need to start antibiotics right away. I think getting the confirmatory study is important and then if that is positive, then realize that other things, including viruses, can cause cough in an infant. So just because they've grown Pseudomonas for the first time, we should get that second culture to confirm that it is in the airways and then start treatment with the eradication protocol. A protocol then would consist of 28 days of nebulized antibiotic, usually an aminoglycoside such as tobramycin, and then in the US 14 days of oral agent (usually) or IV ciprofloxacin.

Judicious use of antibiotics is important because all of these antibiotics have side effects, and as I stated earlier, tobramycin has nephrotoxic side effects. These side effects are cumulative, so the more often you use it, the more likely you'll have some toxicity. Toxicity is probably lower in the inhaled antibiotics than in the oral or IV antibiotics, but it can occur with any of those antibiotics.

MR. BUSKER: And our second learning objective: identifying patients who would benefit from the initiation of cycled inhaled antibiotics. Dr. McCoy?

DR. MCCOY: As in our 8 year old patient with several positives for Pseudomonas, we may not be successful at eradication. In that case, if we don't eradicate, it's time to consider cycling month on/month off inhaled antibiotics for that patient. Certainly we could increase the chest physiotherapy, but I'd like to point out that that should be done judiciously because that's a very time consuming addition and likely to lead to nonadherence. Then other therapies may be needed to support the patient as well.

MR. BUSKER: And finally: identifying the inhaled antibiotic needs for the teenage patient.

DR. HEINTZ: I think for the older teenage patient, when we're already on an on/off cycle with the inhaled tobramycin, adding aztreonam or another inhaled antibiotic would probably benefit this patient a lot. In cases where PFTs are declining and the patient is being admitted quite often for a CF exacerbation, it's important to think about adding another antibiotic to the regimen. But again, this case screams nonadherence, and so while you could add all those things, I would do that after only thinking about it for a while. I might want to try to improve her CPT technique such as the Huff cough that she wasn't doing well. I'd also want to try to improve her nutrition, because that is huge and can affect lung function, as well. And then before adding a new antibiotic or more chest vest therapy, because every time we add something the adherence rate seems to go down in these patients. Trying to maximize their current therapies and then possibly adding an inhaled antibiotic would be useful.

MR. BUSKER: From the Pediatric Cystic Fibrosis Center at Nationwide Children's in Columbus, Ohio, Dr. Karen McCoy and Dr. Daniel Heintz, thank you both for being part of this eCysticFibrosis Review podcast.

DR. MCCOY: You're welcome, and it has been my pleasure.

DR. HEINTZ: Thank you, I've really enjoyed this a lot.

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