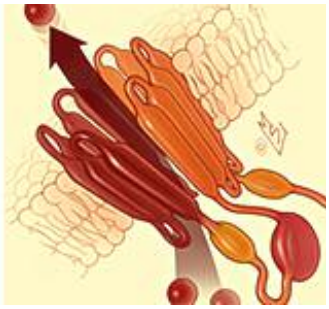

INTERVIEW WITH DR. JAY P. CLANCY: TRANSCRIPT

DR. PATRICK FLUME: I'm Dr. Patrick Flume, guest author of this *e*Cystic Fibrosis Review Special Edition. I am professor of medicine in pediatrics at the Medical University of South Carolina and I'm speaking with Dr. Jay P. Clancy who is the Gunnar Esiason/Cincinnati Bell Chair, research director of the Division of Pulmonary Medicine, and professor in the Department of Pediatrics in Cincinnati Children's. JP, thank you for joining us, today.

DR. JAY P. CLANCY: Thank you for the invitation. It's a pleasure

DR. PATRICK FLUME: JP, I want to talk about your patients who have chronic pseudomonas airway infection. How do you use inhaled antibiotics for these patients?

DR. JAY P. CLANCY: Being a pediatrician, I would say that our number of patients with chronic pseudomonas infection is fewer than it was a few years ago, but I will also note that it's still a significant problem in pediatrics, more commonly in our adolescent population as opposed to young children, where we're frequently eradicating instead of treating chronically. But pseudomonas is a significant problem and burden, and in my experience we typically use cycled inhaled antibiotics for most of our patients. We use the two most common FDA approved preparations, either one of the tobramycin type of preparations, or Cayston, or aztreonam, for inhalation.

DR. PATRICK FLUME: So you generally following the labeled regimen of every other month therapy. Do you use continuous therapy with some patients?

DR. JAY P. CLANCY: In general I use inhaled antibiotics on an alternate month schedule, but in some patients I have chosen to use continuous inhaled antibiotics. Those are typically patients who have had a harder time finding stability, show clear increase in symptoms when they are off inhaled antibiotics, and after talking with them and reviewing the literature and the safety information have felt comfortable that this was a better option for them in my professional opinion.

DR. PATRICK FLUME: In patients in whom you do choose to use continuous therapy, do you generally use a single antibiotic on a continuous regimen or do you use an alternating antibiotic regimen?

DR. JAY P. CLANCY: I have more commonly used a single agent, more for simplicity than anything else. We have also mixed it up for patients and gone with different antibiotics but not in a specific 28 day on/28 day off cycle. For example, we may go six months with a certain antibiotic and then feel it's time to make a change for different reasons. Sometimes the decision driven by third party payers but sometimes it's driven by a perception that the drug is not providing the benefit it had previously. We've certainly been open to using the alternate month approach, but usually for simplicity the families I've worked with have been happy with a single agent and periodically revisiting its continuous use.

DR. PATRICK FLUME: I want to ask you about the study we did using continuous alternating therapy, affectionately named the CAT trial, in patients with CF. I know you're familiar with the study and the data; what are your impressions of the CAT trial?

DR. JAY P. CLANCY: It was a little frustrating. Hopefully in my previous comments I alluded to basing our use of continuous antibiotics on professional opinion, which is not evidence based,

but rather is driven by experience and conversation, and gleaning what we can from other evidence based applications. I've felt CAT was a valuable and important study that will hopefully give us some clarity about the utility of using a continuous antibiotic approach. We were very active in that trial and felt it would bring valuable information to the field.

My observations in looking at the results are that the study could not be completed for a variety of reasons, including competing trials and adoption of a continuous nebulized antibiotic approach by care providers, both of which undermined our ability to effectively recruit into the trial. When looking at the data that's been presented and is approaching publication, it certainly all points to the direction of a benefit and suggests an improvement in symptoms and time to pulmonary exacerbation and frequency of exacerbation, and possibly even lung function. None of those even met statistical significance, but all trended in what I consider the right direction towards benefit of continuous therapy. Taking all that information together provides me at least some assurance that this is a good fit for some of our patients.

DR. PATRICK FLUME: So based on those study results, will that have any impact on your future use of inhaled antibiotics?

DR. JAY P. CLANCY: I think when I talk with families about this option, I can tell them that although the studies were small and therefore underpowered to demonstrate the impact we would expect, a number of trends suggested CAT was beneficial and well tolerated and didn't seem to be associated with any real change in the microbiology or in the resistance pattern. CAT also didn't seem to have any safety signals for patient symptoms or exacerbations. Putting all that together, I feel I have more confidence making this choice than I had prior to the presentation of the CAT data.

DR. PATRICK FLUME: I'm looking forward to the reaction from the community once the publication is out there. JP, I want to thank you for being part of this *e*Cystic Fibrosis Review Special Edition program.

DR. JAY P. CLANCY: You're very welcome, I appreciate the opportunity to talk with you about this and share my experiences, and I hope they're valuable to our understanding and use of antibiotics to manage CF chronic infections.