



# STUDENT CLINICAL DIGEST

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## Clinical Pharmacist Focus



Michael Neville, Pharm. D., BCPS, FASHP

*By Khushbu Tejani, Pharm D. Candidate*

In this issue, we meet Dr. Michael Neville, a clinical pharmacist as well as former Clinical Associate Professor at the College of Pharmacy. Dr. Neville completed his PGY1 residency at Emory Hospital and worked there as a clinical pharmacist in the following years. Prior to leaving the College in December to assume responsibilities as the Assistant Dean of Student Affairs at Wingate School of Pharmacy, he was able to share with us his many clinical experi-

ences and humble advice to our students.

Why did you decide to pursue a residency?

I decided to pursue a residency because of the opportunities available to me as a 4th year student on rotation at Emory University Medical Center. During this APPE, it was the 1st time I saw pharmacist working with the surgery team, internal medicine, intensive care unit, and transplant. What really impressed me was seeing the pharmacists being proactive and contributing to patient care in a way that I never saw before. While there, they got to know me and asked me to consider applying for their residency program. At that time, it was a great opportunity that I knew I didn't want to pass up.

Why did you choose not to specialize and do a PGY2?

At the end of my PGY1, I was more of an internal medicine clinical pharmacist and like the variety of disease states encoun-

tered. I wanted to be a generalist and didn't want to specialize out of fear of being too narrowly focused and lacking variety. I liked being able to dip my feet in other fields, and this has really helped me in the positions I've held.

What made you switch from hospital to academia?

Someone told me many years ago they thought I would be a really great teacher and other people pointed it out a few more times during my career. Both my parents come from an educational background and wanted me to follow. I initially did not want to pursue academia but it runs in my blood. I enjoy teaching because I struggled a lot while a student myself so I can relate to students who struggle. I enjoy seeing those people learn things, see the light bulb come on, and for them to realize they can really learn the stuff and do well with it in the future.

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**By Marisa Fortunato**

## Pharmacist's Potential Role in the Ebola Outbreak

*By Brittany Chambers*

With the emergence of the Ebola virus outbreak spreading to the United States in the fall of 2014, widespread panic has set in among the population. The outbreak began in Guinea in March of 2014 and with no therapies or vaccines against this deadly disease, it spread to at least seven other countries by October of 2014, including the United States. The current outbreak is the largest

and most widespread Ebola outbreak since the virus was first discovered in 1976, according to the World Health Organization. There are 5 species of the Ebola virus and the most recent outbreak in 2014 was caused by the Zaire species. Ebola virus disease (EVD) is a severe illness that can be fatal, especially if untreated. Currently, there are no FDA-approved antiviral treatments for EVD but supportive care is pro-

vided as needed and can significantly increase the chance of survival (1). There are currently two experimental vaccines, cAd3-ZEBOV and VSV-EBOV, which are undergoing Phase I trials that began in September and October of 2014 (2). If Phase I trials are successful, it is thought that these vaccines will be put on the fast-track to FDA approval for use in the current Ebola outbreak; Continued on Page 2

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### Hysingla ER (hydrocodone):

Hysingla ER is a long-acting hydrocodone product that was approved by the FDA in November 2014. It has been approved for use in patients who require chronic management of severe pain and who have failed previous therapies. It is available in strengths of 20 mg-120 mg hydrocodone and is designed to be taken once every 24 hours. Given the high potency of this product and the already widespread problem of abuse of opioid painkillers, a high potential for misuse exists. In an attempt to solve this problem, Hysingla ER has been formulated with unique physical and chemical properties designed to deter its abuse. The tablet itself is difficult to break and crush, which will make alternate routes of ingestion more challenging. Additionally, it does not dissolve easily, forming a viscous gel instead of a solution, making injection difficult. It is the hope of the manufacturer, Purdue Pharma L.P., that Hysingla will provide an effective therapeutic option for patients who need chronic pain management, while simultaneously cutting down on the potential for its abuse.

#### References:

FDA News Release. "FDA approves extended-release, single-entity hydrocodone product with abuse-deterrent properties". November 20, 2014. <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm423977.htm>

How would you describe your typical workday as a resident and even the few years after residency?

Emory residency was very intense. I wasn't really a great student in pharmacy and really only began to understand and focus on my work at the end of my degree. I knew the residency was intense but still decided to do it. The program is laid out with an orientation session at the beginning followed by month-long experiences in indifferent specialties such as surgery or oncology, precepted by different clinical pharmacists. The resident is also assigned a clinical pharmacist to be the overall mentor/advisor as a consistent presence and guide. This clinical pharmacist is helpful when you do your grand round presentation and research project. The research project is intense for those who haven't completed a research project. In addition to that, there are also several longitudinal projects and

smaller projects for each rotation.

The day-to-day activities are really varied depending on the rotation. On some services, the team rounds twice a day, such as the ICU rotation, but others may only do once a day.

When you were the director of the residency program, what factors did you look at in your applicants?

We looked for applicants who were well rounded. Because our program had several residents (4 or 5), we needed them to work well together and looked for these characteristics during the interview. We also looked for those who weren't too "needy" as well and whether our program was a good match for what they were looking for in a residency. Some applicants may have had multiple degrees whose needs were more than what we could offer. Those who are self-directed and motivated really stood out for us. We also sought

those who are willing to take constructive criticism and able to be time managers. We try to figure out all of these characteristics and skills during the interview process. By using multiple preceptors to ask different questions, we were able to know more about these skills and the candidate's personality, motivation, and needs. We may even give a short exam and afterwards, we would get together and rank each individual candidate and choose the ones who would do well and fit well into our program.

How flexible were the rotations?

There are some rotations that their program considered to be essential or required, but also reserved a few months where the residents were able to choose certain rotations in which they showed more interest such as bone marrow transplant.

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## Pharmacist's Potential Role in the Ebola Outbreak

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by Brittany Chambers

this is where a potential role for pharmacists could come into play. cAd3-ZEBOV is derived from a chimpanzee adenovirus and is genetically engineered to express glycoproteins from both the Sudan and Zaire species of the Ebola virus to generate an immune response (2). VSV-EBOV is a recombinant vesicular stomatitis virus-based vaccine that encodes for the Ebola virus (EBOV) glycoprotein in place of the of the vesicular stomatitis virus (VSV) glycoprotein to provoke an immune

response against the Ebola virus (2). Pharmacists have gained a large and vital role in providing immunizations and with the panic and fear of the current Ebola outbreak, administering vaccinations against the Ebola virus may become a primary duty of pharmacists, if and when they are approved.

#### References:

WHO: Ebola Virus Disease update, 1 Sept. 2014. Web. 24 Nov. 2014. <<http://www.who.int/mediacentre/factsheets/fs103/en/>>.  
Gao J, Yin L. "Drug Development for Controlling Ebola Epidemic - A Race against Time." *Drug Discoveries & Therapeutics* 8.5 (2014): 229-31. Web. 24 Nov. 2014. <[https://www.jstage.jst.go.jp/article/ddt/8/5/8\\_2014.01040/\\_article](https://www.jstage.jst.go.jp/article/ddt/8/5/8_2014.01040/_article)>.

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What educational steps did you take to prepare yourself for residency?

Applying to residencies today is very different than when I was a resident, so I'll speak on what I understand about residencies today and my experience as a residency director. ASHP would love for all pharmacy graduates to pursue a residency but with the statistics of how many positions and applicants are available, it's not possible for everyone to match. People really need to think about how to make themselves more

competitive. As a previous residency director, we certainly look at academic performance but also naturally looked at those with a 3.4/3.5 GPA who also participated in community work, pharmacy organizations, and any leadership positions. We found that leadership roles helped us find residents who are responsible and self-motivated and essentially didn't need to hold our hands when given directions. Things that people are doing today include presentations, publications, research projects, community involvement, posters, and anything to separate themselves from

their classmates. You don't need to be worry so much during 3rd year about presentations and publications, but when 4th year begins, you want to think early on about doing a residency. Figuring this out late in the game will leave you with little time to do everything you want to make yourself stand out. Students can start on club leadership and volunteer work to start building their CV early and then add on to it during their 4th year with publications and presentations.

**“Students can start on club leadership and volunteer work to start building their CV early and then add on to it during their 4<sup>th</sup> year with publications and presentations”**

## Denying Immunization: An Epidemic

By Haylee McCoy

Vaccinations have been a recent topic of controversy among many Americans, especially some parents, as there have been many misconceptions to spread like wild fire. Although many of these rumors have no backing scientifically, there are parents who are electing not to vaccinate their children as suggested by the CDC and vast majority of the medical community. It is as important as ever for health care providers, including pharmacists, to become educated on the importance of immunizations, what could happen as vaccination rates decline, and be able to educate their patients on such.

Due to vaccination, smallpox has been completely eradicated from the entire world. Other potentially devastating diseases including measles, rubella, diphtheria, polio, and pertussis have all but disappeared from America. To paint a more vivid picture, the CDC states that “more than 15,000 Americans died from diphtheria in 1921, before there was a vaccine. Only one case of diphtheria has been reported to CDC since 2004.”<sup>1</sup> A goal of immunizing entire populations is to achieve herd immunity so that if one of these rare diseases is introduced (often through travel to other countries) it will not become an epidemic because those exposed who have been vaccinated are immune and can not get nor

carry the disease. Vaccines are not only to protect ourselves, but all of those around us as well. When disease is introduced to an area with low vaccination rates, outbreaks occur. This has happened in 2014 with regards to measles (Figure 1). There have been at least 603 cases this year which is the highest number of cases since measles elimination was documented in 2000.<sup>2</sup> In 1979, the number of pertussis cases and deaths skyrocketed in Japan because of a massive decrease in pertussis vaccination to only 10%. There were more than 13,000 cases and 41 deaths as opposed to 393 cases in 1974 before vaccination declined.<sup>1</sup>

To educate patients, it is important to understand what misconceptions they believe. Leading the way in controversies is the notion that the measles-mumps-rubella (MMR) vaccine and thimerosal, a preservative in some vaccines, cause autism in children. The article by AJ Wakefield et al. that initially suggested the relationship between the MMR vaccine and autism was fully retracted because some of the elements were proven false.<sup>3</sup> Additionally, the topic has been intensively studied and no scientific connection between the vaccine and autism has been made.<sup>4,5</sup> There are no routinely recommended pediatric vaccines that

contain thimerosal.<sup>3</sup>

Additional barriers include religious and moral concerns and the notion that the HPV vaccine may promote promiscuity.<sup>3</sup> Such cases may be handled on an individual basis, but the importance of vaccinations should be addressed as well as risk/benefit evaluation.

There are many other misconceptions regarding vaccinations out there. It is important that healthcare providers be educated and prepared to discuss them with their patients. This includes providing them with the information necessary to increase their patients' understanding and debunk the myths in order to protect our country and the world from deadly, but avoidable diseases.

### References

1. "What Would Happen If We Stopped Vaccinations?" *Vaccines and Immunizations*. Centers for Disease Control and Prevention, 19 May 2014. Web. 24 Nov. 2014.
2. "Measles Cases and Outbreaks." *Measles (Rubella)*. Centers for Disease Control and Prevention, 04 Nov. 2014. Web. 24 Nov. 2014.
3. Chatterjee, Arubana, and Catherine O'Keefe. "Current Controversies in the U.S.A regarding Vaccine Safety." *Expert Review of Vaccines* 9.5 (2010): 497-502. *Pubmed*. Web. 24 Nov. 2014.

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### What advice do you have for students who are interested in residency?

What I tell people who are on the fence about residency is that a lot of people think about “living in the now” vs “living in the future”. It is a long journey to get here but also taking the 2 years to do a residency also allows many doors to open and gives skills sets that you might not get outside of a residency. Academia is also very interesting. As a faculty member, we have had several faculty searches and some departments may not even consider someone without a PGY1 and/or PGY2. To open these doors, two year of residency training may be helpful. It’s not necessarily the “be all end all” for an academic position because it doesn’t train you for academia but more for

how to treat patients. Searching online at job criteria really helps because certain positions may require residency training. Current graduates have the Internet at their disposal and can really use the resources that have recently developed with job searches. Having the mentality that I have community if anything, is not really the case anymore. Today, community pharmacists are doing immunizations, therapy management, which is also requires a lot of training and experience. My experience is you can never go wrong with additional education especially before building a family and having an income. While you have no money, it is a lot easier to live off a smaller income until you finish training.

### What was one of your most memorable experiences?

I think my most memorable experience is just really enjoying the rounding and working closely in an academic medical center with other disciplines to take care of patients. I thought it was really great, and I felt like I made a difference for people in their care and could be proactive in their care. It was a challenge to keep up in the latest and greatest therapies but working as the residency director and an academic professor in the nursing school at the same time was great and difficult job. I was able to learn a lot about teaching and pharmacology, which allowed me to keep up with current therapies. I used the information I gained from the hospital to teach and the information I learned while teaching allowed me to apply the newest therapies in the hospital and stay up to date on new findings.

### Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass Mixed Pollens Allergen Extract)



Oralair was approved in April 2014 for the treatment of grass-pollen induced allergic rhinitis with or without conjunctivitis. It is an immunotherapy agent that contains pollen extracts from five different grasses. Oralair is approved for use in patients aged 10-65 who have had positive skin testing to confirm allergy to any of these grass species. It is available in 100 IR (index of reactivity) and 300 IR sublingual tablets. The daily dose is 300 IR once daily for adults; children aged 10-17 should be dosed as follows: 100 IR on day 1, 200 IR on day 2, and 300 IR on day 3 and thereafter. Treatment with Oralair should be initiated 4 months before the onset of pollen and should be continued throughout the pollen season. The very first dose needs to be administered in a healthcare setting with 30 minutes of monitoring for severe allergic reactions. Subsequent doses may be taken at home, but the patient should be prescribed an epinephrine auto-injector in case allergic reactions are experienced in the future. Oralair is a pregnancy category B drug; it is not known if Oralair is excreted in breast milk, so women who are nursing should avoid use of this therapy.

#### References:

Oralair [package insert]. Lenoir, NC: Greer Laboratories. <<http://www.fda.gov/downloads/BiologicsBloodVaccines/Allergens/UCM391580.pdf>> <http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/1313/oralair-sweet-vernal-orchard-perennial-rye-timothy-and-kentucky-blue-grass-mixed-pollens-allergen-extract>

## Dyslipidemia Management Guidelines: A Battle Field

By Huong Pham

### Dyslipidemia Management Guidelines: A Battle Field

Dyslipidemia is a widespread problem in America. According to the American Heart Association, 43% or 98.9 million Americans over 20 years of age have a total cholesterol level of 200 mg/dL or higher.<sup>1</sup> Hyperlipidemia is one of the modifiable risk factors for heart disease, a leading cause of deaths (600,000 people annually) in America.<sup>2</sup> Dyslipidemia management becomes very important in primary and secondary heart disease prevention; however, the landscape for management of dyslipidemia has changed dramatically since the introduction of the newest lipid guidance. The 2013 American Heart Association/American College of Cardiology Guideline on the Treatment of Blood Cholesterol (2013 AHA/ACC) was a long awaited and much anticipated guideline replacing the National Cholesterol Education Program Adult Treatment Panel III Guidelines (ATP III) which has been the primary hyperlipidemia guideline since 2001. The evidence-based 2013 AHA/ACC lipid guide-

line recommendations are based the results of many clinical trials evaluating the benefits of statin therapy in preventing atherosclerotic cardiovascular (ASCVD).<sup>3</sup> This guideline focuses on statin therapy and provides minimal recommendations regarding the other available lipid-lowering therapies.<sup>4</sup>

The 2013 AHA/ACC guideline identifies four statin benefit groups which include Clinical ASCVD—secondary prevention, Primary LDL-C  $\geq 190$  mg/dL - primary prevention, Age 40-75 with diabetes & LDL-C 70-189 mg/dL - primary prevention, Age 40-75 with LDL-C 70-189 mg/dL, and estimated 10-yr ASCVD risk  $\geq 7.5\%$  - primary prevention. It introduces a new tool to calculate 10-year ASCVD risk for patients between the ages of 40 – 79 years of age. This tool is available online and found on apps for Android and iPhone platforms. It replaces the Framingham CVD risk calculator used in ATP III which did not encompass cerebrovascular risk.<sup>5</sup> There have been some initial concerns that the 10-year ASCVD risk calculator may overestimate risks in

some patients.

Perhaps the most notable change in the 2013 AHA/ACC guideline is that target LDL values are no longer the primary focus of treatment. To some extent, having no fixed goals is a more evidence-based and realistic approach in lipid management. With the previous LDL targets in the ATP III guidelines, many patients were unable to achieve their treatment goals.<sup>7,8</sup>

The 2013 AHA/ACC focuses on statin therapy for the 4 statin benefit groups; however it carries certain limitations which need addressing to better manage patients with dyslipidemia.

#### References

Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics – 2013 update: A report from the American Heart Association. *Circulation* 2013;127:e6-e245.

Centers for Disease Control and Prevention. (2014). FastStats. Retrieved from <http://www.cdc.gov/nchs/fastats>.

Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013;129:S1-S45.

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Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA* 2001; 285:2486–2497.

Akosah KO, Schaper A, Cogbill C, et al. Preventing myocardial infarction in the young adult in the first place: how do the National Cholesterol Education Panel III guidelines perform? *J Am Coll Cardiol* 2003;41:1475–9.

Hecht HS, Superko R. Electron beam tomography and national cholesterol education program guidelines in asymptomatic women. *J Am Coll Cardiol* 2001;37:1506–11.

Arnett DK, Jacobs Dr Jr, Luepker RV, Blackburn H, Armstrong C, Claas SA. Twenty-year trends in serum cholesterol, hypercholesterolemia, and

cholesterol medication use. The Minnesota Survey, 1980 – 1982 to 2000 – 2002. *Circulation* 2005;112:3884–3891.

Lloyd-Jones D, Adams RJ, Brown TM, et al. Executive summary: Heart disease and stroke statistics – 2010 update: A report from the American Heart Association. *Circulation* 2010;121:948–954.

## Brincidofovir: The Potential New Drug for the Treatment Ebola

By: Payal Kakadiya

Ebola has made its comeback and this time it has affected people in the U.S. Because of the outbreak of the deadly virus, the research and development sectors of various pharmaceutical companies have gone head first into finding a cure.

Chimerix, Inc. is the developer of brincidofovir, an antiviral for treatment of DNA viruses such as cytomegalovirus, adenoviruses, BK virus, small pox, and herpes simplex virus. It is also believed that it may have potential as treatment of the Ebola virus.

Brincidofovir is the prodrug of cidofovir. Cidofovir resembles the structure of cytidine, a DNA nucleotide. It is used up by DNA polymerases because it looks similar and the incorporation of cidofovir causes inefficient DNA synthesis, thus inhibiting viral replication. Brincidofovir was created by adding a lipid chain making it more potent, increasing its oral bioavailability, and reducing kidney toxicity. Because of its increase in lipophilicity, brincidofovir releases cidofovir intracellularly increasing its activity against viral DNA.

The drug is currently in Phase III clinical trials for use against the cytomegalovirus and adenovirus and has received the FDA Fast Track Designation. Because of brincidofovir's unique inhibition of viral DNA replication, the FDA authorized the Emergency Investigational New Drug application of brincidofovir on October 6, 2014 for the treatment of the Ebola virus.

Brincidofovir was given to the first patient in the U.S. diagnosed with Ebola in Dallas. It was administered six days after the hospital admission, however, the patient passed away four days later. The patient had been critically ill so the effects of the antiviral were unknown because he could have died from not being able to tolerate the side effects or from his deteriorating status. Brincidofovir was also given to an Ebola patient at Nebraska Medical Center. He was pronounced Ebola-free and released from quarantine.

The antiviral has now moved into Phase II trials to test for its safety, tolerability, and efficacy in the treatment of the Ebola virus. It is currently available in the tablet form for immediate use in clinical trials. With

brincidofovir being the only potential treatment for the Ebola virus, it becomes a commodity and worth millions. However, it must still undergo Phase III trials of FDA approval in order to become the go-to treatment for Ebola. With research underway, there is hope that brincidofovir will follow through and become the leading treatment for all types of DNA viruses.

### References

Florescu, D.F., Keck, M.A. Development of CMX001 (Brincidofovir) for the treatment of serious diseases or conditions caused by dsDNA viruses. Expert Review of Anti-Infective Therapy. 2014,12(10):1171-1178.

Quenelle, Debra C.; Lampert, Bernhard; Collins, Deborah J.; Rice, Terri L.; Painter, George R.; Kern, Earl R. Efficacy of CMX001 against Herpes Simplex Virus Infections in Mice and Correlations with Drug Distribution Studies. *The Journal of Infectious Diseases*. 2010;202 (10):1492–1499.

<http://www.chimerix.com/c/discovery-clinical-trials/brincidofovir-ebola.php>

Contrave (naltrexone HCl and bupropion HCl extended-release):



Contrave was approved in September 2014 as a weight loss agent. In combination with exercise and calorie-reducing lifestyle modifications, it is approved for use in adult patients with a BMI of 30 kg/m<sup>2</sup> or higher or in patients with a BMI of 27 kg/m<sup>2</sup> or higher with at least one weight-related comorbidity. Contrave combines the action of naltrexone, an opioid antagonist, with that of bupropion, a norepinephrine and dopamine reuptake inhibitor. These agents are thought to work together to decrease appetite and curb hunger cravings. A strict dose titration schedule lasting 4 weeks must be followed when starting Contrave, and evaluation of efficacy is needed at 12 weeks. If there has not been at least a 5% weight reduction by week 12, Contrave should be discontinued. A number of side effects may be associated with Contrave, including a black-boxed warning of increased risk of suicide due to bupropion. Patients should therefore be carefully evaluated before the decision is made to initiate Contrave.

### Sources:

*FDA News Release. "FDA approves weight-management drug Contrave." September 2014.* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm413896.htm>  
*http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100032/contrave-naltrexone-hcl-and-bupropion-hcl*