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Arnold & Marie Schwartz College of Pharmacy & Health Sciences

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AMSCOP-ACCP Student Chapter Synopsis

The Long Island University (LIU) American College of Clinical Pharmacy (ACCP) student chapter was founded in 2002, with a goal to provide opportunities for students to strengthen clinical skills, promote professional growth, and advance the future of pharmacy. Since 2002, Dr. Plakogiannis has served as our chapter's faculty advisor. In the fall semester of 2017, Dr. Mo joined the LIU-ACCP as a faculty co-advisor to further assist student members in their academic and professional development endeavors. Since the foundation of our chapter, we have grown into one of the leading student organizations at LIU Pharmacy. We take great pride in our participation in a variety of activities including professional development programs, community outreach, health fairs, and social events. Aligning with the mission and core value of the ACCP, we are committed to promoting excellence in patient care through research and professional

development. The LIU-ACCP student chapter was involved in many events and activities during the previous academic year. In October 2016, 50 student members attended the Juvenile Diabetes Research Foundation (JDRF) One Walk. Our chapter was able to raise over $1,000 through several bake sales and an online fundraising campaign and donate it to the JDRF in an effort to support type 1 diabetes (T1D) research. Additionally, in collaboration with American Pharmacist Association (APhA) and Phi Delta Chi, we made an effort to promote public awareness of the importance of T1D research both on campus and via social media. This year, our chapter also participated in the Relay for Life event where we raised over $1,000 through bake sales to support the American Cancer Society. One of the important activities that the LIU-ACCP student chapter was involved in this year was to co-host a fundraising banquet for Syrian refugees with Kappa Psi Pharmaceutical Fraternity, LIU Muslim Student Association, and International Fortune for Children Non-Profit Organization. The event was successful, and we were able to raise more than $ 1,000, which will be used to fund the Syrian Civil Defense volunteers or White Helmet. Along with the banquet, we organized a clothing drive on campus. The collected clothes were donated to a local mosque. As a result of our dedicated voluntary services, our chapter received the Philanthropy award from the LIU Student Government Association.

In the spring semester of 2017, our chapter provided a blood pressure screening event to LIU faculty, staff, and students. During the event, students measured blood pressures and increased awareness of blood pressure goals and risk factors for cardiovascular diseases.

The LIU-ACCP student chapter now hosts a monthly Journal Club meeting in hopes of having a better understanding of the research process and developing skills for evaluating medical literature.

-Yoonsun Mo, PharmD & Roda Plakogiannis, PharmD

Meet Our Faculty Advisors

Yoonsun Mo, PharmD, BCPS, BCCCP

Roda Plakogiannis, BS, PharmD, BCPS, CLS, FNLA

DR. YOONSUN MO received her Pharm.D. degree from Creighton University and completed a PGY-1 Pharmacy Practice Residency at Barnes-Jewish Hospital in St. Louis, Missouri and a PGY-2 residency in Critical Care at University of Washington Medical Center in Seattle, Washington. After completing residency trainings, she pursued her career as a clinical pharmacy specialist in Surgery/Trauma Intensive Care Unit (ICU) at Cedars-Sinai Medical Center. In the fall of 2016, Dr. Mo joined Long Island University (LIU) Pharmacy as an Associated Professor of Pharmacy Practice. Prior to joining LIU Pharmacy, she taught as an Assistant Professor in the Department of Pharmacy Practice at the Western New England University College of Pharmacy in Springfield, Massachusetts. She also served as an ICU pharmacy specialist at Mercy Medical Center. Dr. Mo is currently practicing in the medical ICU and precepting pharmacy students at Brookdale University Hospital and Medical Center in Brooklyn, New York.

DR. RODA PLAKOGIANNIS is an associate professor of pharmacy practice at the Arnold & Marie Schwartz College of Pharmacy. She received both her Bachelor of Science in Pharmacy and traditional Doctor of Pharmacy degrees from the Arnold & Marie Schwartz College of Pharmacy & Health Sciences. Dr. Plakogiannis completed an ASHP-accredited specialized pharmacy residency in primary care at the Bay Pines Veterans Medical Center in Tampa, Fl. She is a Board Certified Pharmacotherapy Specialist, a Diplomat and Fellow of the Accreditation Council for Clinical Lipidology and a Board Certified Clinical Lipid Specialist. She serves as one of the Board of Directors for the National Lipid Association and on the Accreditation Council for Clinical Lipidology Board of Governors. Dr. Plakogiannis also serves as the Adverse Drug Reactions Section Editor for the Journal of Pharmacy Practice. Dr. Plakogiannis practices at NYU Langone Health predominantly managing patients with hyperlipidemia, hypertension, and heart failure. Her scope of practice involves assessing ambulatory patients for medication-related problems, evaluating medication regimens to ensure that they are safe, appropriate, and cost-effective by identifying potential drug interactions, drug-related adverse effects, duplicate therapy, and obstacles/barriers to adherence. She is also the residency program director for a new residency program Long Island University @ NYU Langone Health, with focus on ambulatory care/transition of care and academia.

Clinical Spotlight

Muhammad Effendi, PharmD, PGY-2 Critical Care Pharmacy Resident at Yale New Haven Hospital, Connecticut

1. What is your current role at Yale New Haven Hospital?

I am currently a PGY-2 Critical Care Pharmacy Resident at Yale New Haven Hospital. I also completed my first year residency at the same hospital. I went through the early commitment process and stayed on board for another year.

2. What made you pursue a residency?

Since staring at LIU Pharmacy, I have developed a strong passion for clinical practice and direct patient care with a multidisciplinary approach by working with physicians, nurses, and other health care providers. My residency training allowed me to further develop clinical skills and prepared me to become a better clinical pharmacist. Additionally, I knew I had a desire to

further pursue my interest in critical care and research. In today's work environment, it is important, and now often mandatory, to pursue advanced training to be able to practice in specialized areas (critical care, oncology, pediatrics, etc.).

3. Are you involved in any research? If you are, can you briefly tell me about some of your research?

I am currently working on a few longitudinal research projects. One of my projects is to evaluate patients above 80 years of age who received IV alteplase for acute ischemic stroke in the 3- to 4.5-hour time window. This is an off-label use in which, to our knowledge, no data exist. It is a retrospective study, in which we will assess the safety and efficacy of IV alteplase in this age group in the time period of 3 to 4.5 hours after stoke. Some of the data points we will be looking at include rates of intracranial hemorrhage, modified ranking score upon discharge (level of disability), and stratifying risk factors associated with outcomes.

4. Can you tell me about your AMSCOP post career experience?

My post AMSCOP career experience has been a challenging yet rewarding one. I believe that you get out what you put in. In addition to building upon my clinical knowledge, I have greatly improved other skill sets such as communication, writing, time management, project management, and conflict resolution. Now I truly understand why people say one year of residency is equal to three years of working experience.

5. What do you believe was the greatest lesson AMSCOP has taught you?

The greatest lesson AMSCOP has taught me is with laser focus, a strong passion and desire, and a strong work ethic, you can accomplish whatever career goals you seek out, make advancements in clinical practice, and positively impact patient care. Seeing this directly from many wonderful professors and preceptors, it became engraved in my head that I could accomplish all the things I set out to do. The teaching philosophy founded by Dr. Halstead, known as the father of the modern surgery in the U.S., "see one, do one, teach one", was very much passed down to me from many of the faculty at AMSCOP. I believe this training helped me to advance my career.

-Benazir Choudhury, PharmD Candidate AMSCOP Class of 2019

Guideline Review: 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk

For more than twelve years dyslipidemia management was based on the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (NCEP) Adult Treatment Panel III (ATP III) [1], with an addendum release in 2004. In 2013, the American College of Cardiology and American Heart Association (ACC-AHA) released their guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerosis Risk in Adults. [2] The panel utilized randomized controlled trials and identified four groups of patients that would benefit from statin therapy, allocating the statin intensity for each respective group. Treatment targets for LDL-C and non-HDL-C were removed and instead emphasis was placed on the LDL-C reduction from baseline after statin initiation. In comparison to the traditional management of dyslipidemia, the 2013 ACC/AHA recommendations differed to a marked degree. Subsequently, the National

Lipid Association (NLA), did not endorse these guidelines and released their own Patient Centered Management of Dyslipidemia in September 2014.[3] The NLA recommendations highlighted a patient centered approach, lifestyle modification, screening and classification of lipoprotein lipid levels, atherosclerotic cardiovascular disease (ASCVD) risk stratification with respective treatment goals, targets for interventions, and drug therapy.[4]

Fast forward to 2017, several trials examining the addition of non-statin therapy to statin therapy have either justified their use (ezetimibe, PCSK9 inhibitors), downgraded (bile acid sequestrants), or no longer recommend (niacin), their use. [4, 5, 6] Therefore to address the new data and close gaps in managing hyperlipidemia, the panel reconvened to further evaluate, taking into account cost, tolerability, pill burden, route of administration, potential drug- drug interactions and patient preference. As a result a more comprehensive pathway, highlighting non-statin therapies and reintroducing non-HDL-C and LDL-C goals to the already established four patient statin intensity groups were developed. Both governing bodies of the ACC and the National Lipid Association endorsed this expert consensus decision pathway. [7]

Emphasis on lifestyle modifications is highlighted, consisting of exercise most days of the week, adherence to a heart-healthy diet, smoking cessation, all of which are detailed in the 2013 ACC/AHA Guideline on Lifestyle Management to Reduce Cardiovascular Risk and the National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 2 for lifestyle recommendations for healthy adults and management of dyslipidemias.[8,9,] The panel further recommended monitoring the efficacy of LDL-C lowering therapies, by obtaining an initial fasting lipid panel followed by a second lipid panel 4 to 12 weeks after statin initiation, assessing patient adherence and response to therapy. Determining true statin intolerance by carefully reviewing the patient's signs and symptoms and ruling out other causes of muscle-related statin side effects is also highlighted. In the event the patient experiences a statin related side effect, the patient should discontinue the statin therapy until resolution of symptoms and subsequently be rechallenged on at least 2 to 3 statins, with different metabolic pathways. To further assist the clinician, the ACC Statin Intolerance App, which incorporates the ACC/AHA guideline and the NLA's 2014 Statin Intolerance Panel, for evaluation and management of potential statin-related side effects is recommended to be used. This app assists clinicians with questions to evaluate muscle related symptoms and offers step-by-step guidance on the management of these symptoms.

Like the 2016 Expert Consensus Pathway, ezetimibe and PCSK9 inhibitors are the recommended non-statin therapies, pathways outlines in Figures 1 & 2. Ezetimibe is recognized as the initial non-statin agent in patients requiring an additional < 25% LDL-C lowering. In patients on the maximum tolerated statin-ezetimibe or ezetimibe monotherapy due to statin intolerance, the panel recommends a patient-clinician discussion considering the addition of a PCSK9 inhibitor. In patients with phenotypic homozygous familial hyperlipidemia, PCSK9 inhibitors should be considered before LDL apheresis. PCSK9 inhibitors however are not recommended for use in patients with symptomatic heart failure, maintenance hemodialysis, or pregnant women due to exclusion criteria for the PCSK9 trials.

Bile acid sequestrants have been downgraded and are recommended as secondary agents in patients intolerant to ezetimibe with triglycerides <300mg/dL, despite their lack of evidence for cardiovascular risk reduction in addition to statins. Niacin failed to demonstrate cardiovascular risk reduction and instead caused more harm when niacin/laropiprant was added to simvastatin therapy, despite further LDL-C lowering.[4]

The expert consensus assists in closing the gaps and the inconsistencies in the management of hyperlipidemia amongst healthcare practitioners. Providing helpful guidance in optimal ASCVD risk reduction with the addition of evidence based non-statin therapy.

Figure 1. Four Statin Benefit Groups & Extended Interventions

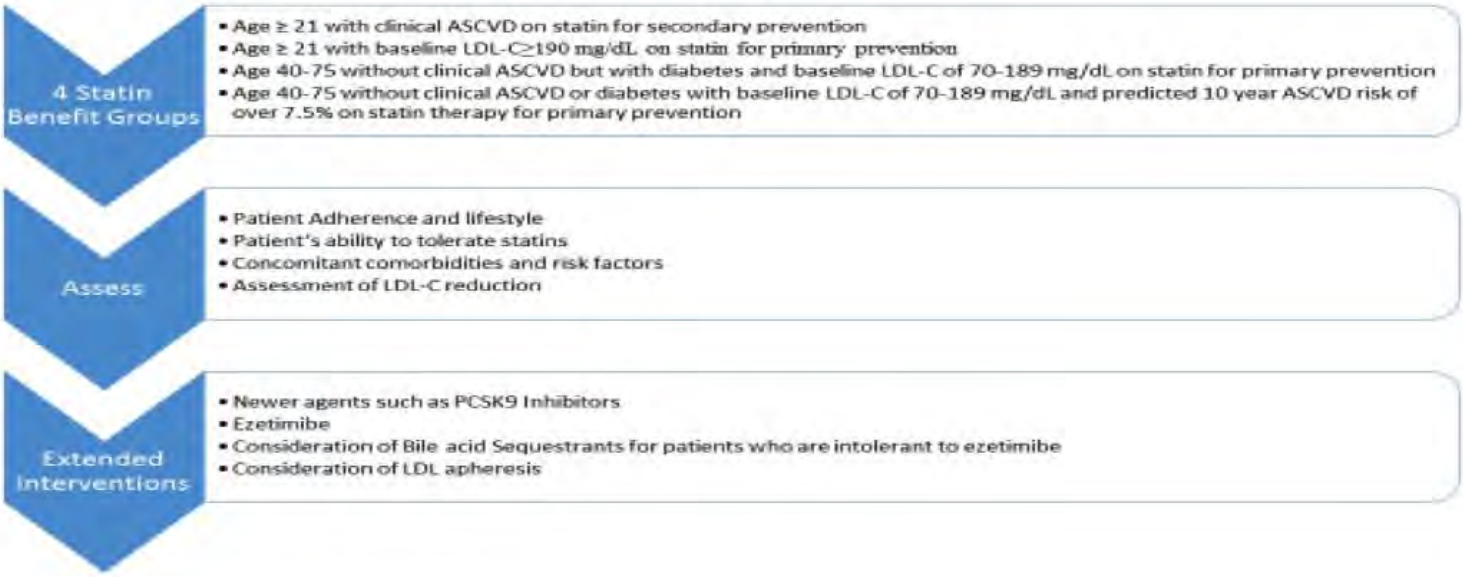
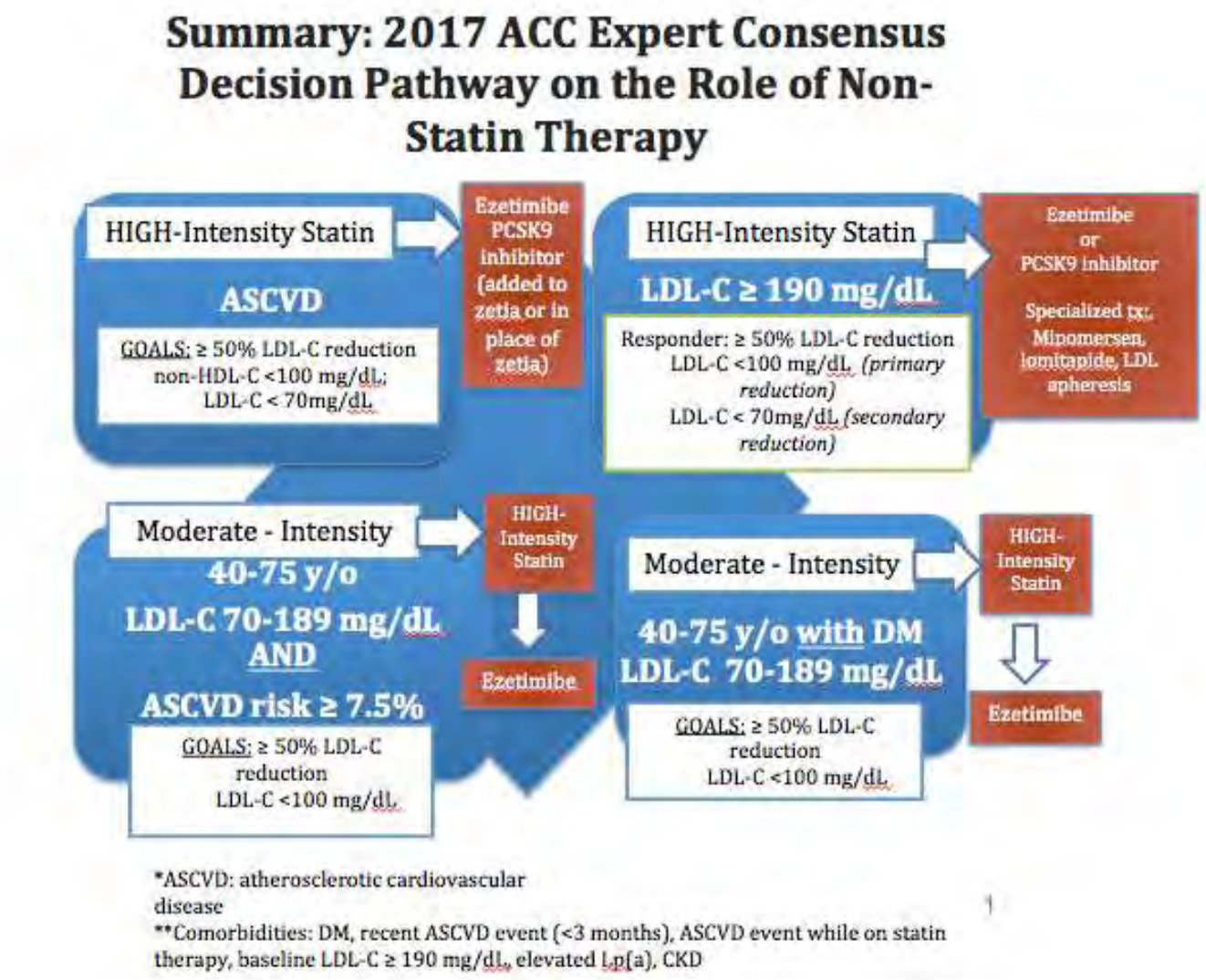


Figure 2. Summary: 2017 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapy



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- Roda Plakogiannis, BS, PharmD, BCPS, CLS, FNLA, Adnan Garrett, and Tayyeb Din, PharmD Candidates of AMSCOP Class of 2019

New Drug Review: Vabomere®

Vabomere® is a combination of meropenem and vaborbactam approved by the Food and Drug Administration (FDA) on August 29, 2017 for the treatment of complicated urinary tract infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae species* complex in patients ≥ 18 years of age.[1-3] The first component of Vabomere® is meropenem, a broad spectrum carbapenem antibiotic effective against the majority of gram-positive and gram-negative aerobes and anaerobes.[4] Meropenem has been used to treat serious bacterial infections including bacterial meningitis, complicated skin and skin structure infections, and complicated intra-abdominal infections.[4] The bactericidal activity of meropenem results from the inhibition of cell wall synthesis by binding penicillin-binding protein targets (PBP).[4] Although meropenem is stable to hydrolysis by most beta-lactamases such as penicillinases and cephalosporinases, it is not stable against carbapenem-hydrolyzing β lactamases.[5] The second component, vaborbactam, is a novel cyclic boric acid beta-lactamase inhibitor that protects meropenem from hydrolysis by gram-negative organisms producing *Klebsiella pneumonia carbapenemase* (KPC) enzymes and other Ambler class A and C enzymes.[5] The combination of meropenem with vaborbactam appears to have little effect on *Acinetobacter baumannii* containing OXA-type carbapenemases or *Pseudomonas aeruginosa* and no activity against bacteria producing metallo-β-lactamase (MBL).[5-7]

The usual dose of Vabomere® for adults is 4 grams (meropenem 2 grams plus vaborbactam 2grams) every 8 hours by intravenous infusion over 3 hours.[1,2] In patients with renal insufficiency (eGFR < 50 ml/min/1.73 m^2), the dose of Vabomere® should be adjusted according to the recommendations of the manufacturer.[1,2] The precautions and warnings for Vabomere® include hypersensitivity reactions, seizure potential, and *Clostridium difficile*-associated diarrhea.[1,2] Additionally, the concomitant use of Vabomere® and valproic acid is not recommended due to their clinically significant interactions, resulting in decreasing plasma concentrations of valproic acid.[1,2]

The FDA approval of Vabomere® was based on data from the TANGO-1 trial, a multi-center, randomized, double blind, double-dummy study.[2] The TANGO-1 study was conducted to evaluate the efficacy, safety, and tolerability of Vabomere® in comparison to piperacillin-tazobactam in the treatment of complicated urinary tract infections in adult patients.[2,3] In this trial, 550 patients were randomized to receive either Vabomere® (meropenem 2g - vaborbactam 2g) (n=273) every 8 hours or piperacillin-tazobactam 4.5 grams (n=273) every 8 hours for up to 10 days. After a minimum of 15 doses of IV therapy, patients who met pre-specified criteria for improvement were switched to oral levofloxacin to complete the treatment course.[2,3] The primary end point was overall success of clinical outcome, defined as a composite of clinical cure and microbiological eradiation

(baseline bacterial pathogen reduced to 10^4 CFU/ml) at the end of IV therapy. The overall success rates in the meropenem-vaborbactam group and piperacillin-tazobactam group were 98.4% and 94.3 %, respectively (95% CI of difference: 0.7-9.1).[2,3] Serious adverse events (SAEs) were observed in 11 patients (4%) receiving meropenem-vaborbactam and 12 patients (4.4%) on piperacillin-tazobactam. The common adverse events for Vabomere®-treated patients included headache, infusion site reactions, and diarrhea.[4] The TANGO-1 study concluded that meropenem-vaborbactam was superior to piperacillin-tazobactam in the primary end point of overall success for the treatment of complicated urinary tract infections. Overall, meropenem-vaborbactam was well tolerated, and the adverse event profile in both groups was similar.

The TANGO-2 is a multi-center, randomized, open-label study of meropenem-vaborbactam that ended early due to superior benefit-risk compared to best available therapy in patients with serious infections caused by carbapenem-resistant *Enterobacteriaceae* (CRE).[7] The interim data from the TANGO-2 study showed that there were significant differences in clinical cure favoring meropenem-vaborbactam over best available therapy. In addition, renal adverse effects were lower in patients treated with meropenem-vaborbactam than best available therapy, particularly among patients who received colistin and aminoglycosides.

The occurrence of CRE isolates is rising substantially worldwide due to the dissemination of pathogens producing carbapenemases including KPC, MBL, or oxacillinase. Infections caused by CRE are difficult to treat and pose a serious health concern because CRE isolates are resistant to nearly all β-lactam agents including carbapenems. Therefore, Vabomere® offers a new potent treatment option for serious gram-negative infections caused by KPC-producing organisms.

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