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GSHP Summer Meeting, July 17-19, 2015
Registration Rates-Early Until 6/1
GSHP Pharmacist Member $170
Pharmacist Non-Member* $250
Resident $85
Technician-Member $90
Technician-non-member* $115
Pharmacy Student member $50
Pharmacy Student non-member* $70

To register:
www.gshp.org//MeetingRegistration.aspx

Room Reservations-If you run into any issue making your room reservation, please contact Steve Glass at 850-906-9206.

The 2015 Summer Meeting will be held at the Omni Amelia Island Plantation, Amelia Island, FL. GSHP has very attractive room rates that start at $177 single/double per night for an ocean view hotel room at the Omni Amelia Island Inn and Beach Club; $149 for a resort view room. To make your reservation, click here:

Hotel Reservations

The GSHP room rate will be honored for three days prior to group arrival and three days after group departure based on availability.

The Plantation has a wide variety of rooms and villas and the link above can help you with any of them.

Click here for villa information, rates, etc.

If you need any assistance with rooms or need more information about the room types that are available, please contact Steve Glass at sglass@gshp.org

There is $10 daily resort service fee this year per room. The resort fee includes:

- Self Parking ($10 daily value)
- Unlimited high speed internet access in all accommodations ($9.95 daily value)
- On-property Transportation ($4.00 daily value)
- Unlimited use of health & fitness center ($20 daily value)
- In Room Coffee Service ($5.00 daily service)
- Meeting Concierge & 24 Public Safety Team
- Local & Toll Free Phone Access

**New Omega-3 Product Approved for Severe Hypertriglyceridemia: Epanova®**

Thanh Vu, 2015 Pharm.D. Candidate, Tarannom Tebyanian, 2015 Pharm.D. Candidate, and Maria Miller Thurston, Pharm.D., BCPS

Mercer University College of Pharmacy

**Background**

Hypertriglyceridemia is a condition in which triglyceride (TG) levels are abnormally elevated, and it may result from a number of factors, including uncontrolled diabetes mellitus, obesity, an unhealthy diet high in alcohol and saturated fat, and/or certain medications. Hypertriglyceridemia has been identified as a risk factor for major coronary events once low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol are controlled. Normally asymptomatic, hypertriglyceridemia is often discovered only after a fasting lipid panel is performed. Patients with severe hypertriglyceridemia (≥500 mg/dL) are at risk of developing pancreatitis, eruptive xanthomas, or lipemia retinalis.

Therapeutic lifestyle changes (TLC) are considered first-line treatment for less severe hypertriglyceridemia. Some over-the-counter (OTC) medications can also help to reduce TG levels, including niacin, fish oil with omega-3 fatty acids, and fiber products such as psyllium. Omega-3 fatty acids from fish and fish oil supplements are known to be effective in lowering TG levels. However, it is essential that OTC medications used have appropriate amounts of EPA and DHA, which is often not the case. Therefore, prescription strength omega-3 products are typically recommended and required for more severe cases. Prior to May 2014, the two prescription products available were Lovaza® (omega-3-acid ethyl esters) and Vascepa® (icosapent ethyl).

**Guidelines**

The ATP III guidelines define differing degrees of hypertriglyceridemia (Table 1). According to ATP III, TG levels ≥500 mg/dL should be the primary treatment target regardless of LDL level, and the recent 2014 National Lipid Association (NLA) guidelines also recommend treatment for very high TG values. The ATP III guidelines recommend fibrates, nicotinic acid, bile acid sequestrants, absorption inhibitors, and omega-3 fatty acids as treatment options for elevated TG levels. The NLA guidelines recommend statin therapy as generally first-line for TG levels of 200-499 mg/dL, TG lowering agents (fibrates, omega-3 fatty acids and nicotinic acids) or statins for patients with TG levels 500-999 mg/dL, and TG lowering agents specifically as first-line for TG levels ≥1000 mg/dL. The Endocrine Society guidelines published in 2012, also recommend fibrates as first-line therapy for severe TG levels ≥1000 mg/dL. The American Heart Association/American College of Cardiology (AHA/ACC) 2013 guidelines provide no specific and detailed recommendations regarding hypertriglyceridemia management.

**Table 1: National Cholesterol Education Program-Adult Treatment Panel III (NCEP-ATP III) Classification of TG levels**

<table>
<thead>
<tr>
<th>Value (mg/dL)</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 150</td>
<td>Normal</td>
</tr>
<tr>
<td>150–199</td>
<td>Borderline high</td>
</tr>
<tr>
<td>200–499</td>
<td>High</td>
</tr>
<tr>
<td>≥ 500</td>
<td>Very high</td>
</tr>
</tbody>
</table>

**Epanova® (omega-3 carboxylic acids)**

In May of 2014, the US Food and Drug Administration (FDA) approved Epanova® (omega-3 carboxylic acids) for the management of severe hypertriglyceridemia as an adjunct to diet. Omega-3 fatty acids include the long-chain alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA). Epanova® is the first FDA-approved omega-3 product available in free fatty acid form. Epanova® is also the first prescription omega-3 agent to have a dosing option as few as two capsules once daily, with or without food. Some possible mechanisms of Epanova® in decreasing TGs involve reducing lipogenesis in the liver and utilizing EPA/DHA which are poor substrates for the enzyme responsible for TG synthesis. There are no known drug interactions with Epanova®, with the exception that it may increase risk of bleeding with concomitant use of anticoagulants. This medication is well tolerated and some common adverse effects of Epanova® are diarrhea, abdominal discomfort and eructation or belching.

**Clinical Trials**

Prior to FDA approval, Epanova® was evaluated in select clinical trials. The Epanova® for Lowering Very High Triglyceride (EVOLVE) study was a randomized, placebo controlled study which demonstrated 25% to 30% reduction in TG levels with 2, 3 and 4 grams of Epanova® daily. However, LDL cholesterol levels were increased by 21%, 16%, and 26% with 2, 3, and 4 g/day, respectively. The Epanova® Compared to Lovaza® in a Pharmacokinetic
Single Dose Evaluation (ECLIPSE) study revealed a therapeutic advantage of Epanova®, demonstrating a dramatically improved bioavailability over Lovaza® in overweight patients following a low-fat diet. The total EPA and DHA concentration during low-fat and high-fat diet was determined to be greater with Epanova® by 4-fold and 1.3-fold respectively; therefore, the free fatty acid formulation of Epanova® is not as affected by meal fat content as compared to Lovaza®. Patients in both studies were instructed to follow the TLC diet prior to and during treatment periods and no severe adverse effects were reported.12 There are currently no studies available which compare the efficacy and safety of Epanova® directly to Vascepa®.

Practical Considerations

Currently, the AHA recommends 2 to 4 grams of EPA and DHA daily to lower TG levels. Each one gram capsule of Epanova® contains 550 mg of EPA and 200 mg of DHA, and the recommended dosage is 2 grams (2 capsules) or 4 gram (4 capsules) once or twice daily.13 The cost of Epanova® has not yet been determined by the manufacturer.6 Epanova® is recommended to be used once diet changes have failed to lower TG levels adequately, and it also has an advantage over Lovaza® due to its enhanced absorption. Pharmacists may play an important role in lipid management, since they can work along with other providers to reinforce the TLC diet and also motivate patients to establish a healthy lifestyle. Furthermore, pharmacists can educate providers regarding OTC and prescription medications available for lowering TG levels. Finally, pharmacists also have a unique opportunity to counsel patients regarding TG lowering medications and they may assist patients with prevention, identification, and management of adverse events.

References


and children is approximately 20 days, and for maximum efficacy doses need to be administered within 35 days of previous dose.\textsuperscript{1,2} Medication interactions have not been reported to occur, but there is an important interaction between palivizumab and the immunoassay to detect the RSV antigen leading to an increased number of false negatives. In patients receiving monthly prophylaxis, a reverse transcriptase-PCR must be used to confirm or deny active RSV infection. In July 2014, the American Academy of Pediatrics (AAP) published updated guidelines for the use of palivizumab.\textsuperscript{[4]-[5]}

Gestational age at birth for administration in premature infants, and contact with siblings or daycare were some of the major changes from previous AAP guidance. Previously, infants born gestational age <34 weeks had many stipulations to qualify. The new recommendation for administration is in children born less than 29 weeks (28 weeks 6/7 days or less) and less than 12 months at the start of the RSV season. Prospective surveillance studies of infants during RSV seasons 2000-2005 throughout North America found no significant benefit in children of older gestational age, or when the child had siblings or attended daycare.\textsuperscript{[6]-[7]}

Children less than 12 months at the start of the RSV season who were born \(\leq 32\) weeks 0/7 days gestational age and required \(>21\%\) oxygen for at least the first 28 days after birth are also recommended to receive monthly prophylaxis. If a child under 24 months of age continues to require therapy with diuretics, corticosteroids, or supplemental oxygen within the six months prior to the start of the 2\(^{nd}\) RSV season then he or she will also qualify for monthly prophylaxis. Chronic lung disease has been shown to be associated with more severe RSV infection, and the use of palivizumab decreased hospitalization due to severe RSV infection in this population.\textsuperscript{1}

While palivizumab is a well-tolerated medication with few adverse events, it is important to identify the patients who would benefit most to avoid administration in those it may not be as beneficial. Palivizumab inhibits the fusion and entry of the RSV into host cells to decrease severity of infection, and does not prevent RSV infection from occurring in all children. The updated AAP guidance for 2014 has more clearly defined the populations which palivizumab will be most advantageous.

\begin{itemize}
  \item 1. The IMpact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from syncytial virus infection in high-risk infants. Pediatrics. 1998;102(3 pt 1):531–537
  \item 3. Synagis\textsuperscript{®} [package insert]. Medimmune., LLC; Gaithersburg, MD; March 2014
\end{itemize}
FDA Revives Compounding Advisory Committee

[April 15, 2015, AJHP News]

Kate Traynor

BETHESDA, MD 30 Mar 2015—When FDA in late February convened a meeting of its Pharmacy Compounding Advisory Committee, the agency essentially resumed a project that had been on hold for more than a dozen years.

Part of that project involved revising FDA's 1999 list of drugs that may not be used for compounding because they are not safe and effective. The development of the list had been shelved after a 2002 Supreme Court ruling invalidated part of the statute by which FDA regulates compounded products.

ASHP Honors Pharmacy Students for Campus, Practice Leadership

3/30/2015

ASHP has recognized twelve pharmacy students for their achievements in campus leadership and pharmacy practice in hospitals or ambulatory care clinics (including professional work experience, internships, and other accomplishments) with the ASHP Student Leadership Award.

The award, sponsored by ASHP and the ASHP Research and Education Foundation, is given to student members in their second through fourth professional years of pharmacy school. The award winners receive a plaque, an ASHP drug information reference library, and a $2,000 cash award.

ASHP Honors Members for Practice Excellence, Leadership

Thirty-Five Pharmacists Designated Fellows

3/27/2015

Thirty-five pharmacists who practice in hospitals, ambulatory care clinics, and other settings have been given the title "Fellow" of ASHP in recognition of the excellence they have achieved in pharmacy practice. The 2015 Fellows will be honored on Tuesday, June 9, 2015, during the ASHP Summer Meetings and Exhibition in Denver.

The ASHP Practitioner Recognition Program rewards excellence in pharmacy practice by granting recognition through the FASHP designation. Members who have achieved FASHP status have successfully demonstrated sustained commitment or contributions to excellence in practice for at least 10 years, contributed to the total body of knowledge in the field, demonstrated active involvement and leadership in ASHP, and have been actively involved in and committed to educating practitioners and others. The program has recognized 838 Fellows since it began in 1988.

New Combination Vaccine Licensed for 4- to 6-Year-Olds

Cheryl A. Thompson

BETHESDA, MD 26 Mar 2015—FDA and Sanofi Pasteur Inc. on Wednesday announced the licensing of a new vaccine for use in children 4 to 6 years of age to complete the diphtheria, tetanus, and pertussis (DTaP) vaccination series and inactivated poliovirus vaccination series.

The vaccine, its labeling (PDF) states, is intended for children who have already received four doses total of Sanofi Pasteur's DTaP vaccine or the company's diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus, and Haemophilus b conjugate (tetanus toxoid conjugate) vaccine.

Label Design May Affect Medication Safety in an OR Crisis

[Journal of Patient Safety (03/07/2015) Estock, Jamie L.; Murray, Andrew W.; Mizah, Margaret T.]

The redesign of medication labels can help prevent some types of medication errors. In one study, 96 anesthesia trainee participants were randomly assigned to either a current or a redesigned label condition. Each participant was the sole anesthesia provider in a simulated operating room scenario and was asked by the surgeon to administer hetastarch to the
Pharmacogenomics Coming to EMRs
Healthcare IT News (03/10/15) Versel, Neil

A pharmacogenomics clinic has opened at NorthShore University HealthSystem in Evanston, IL, among just a handful in the nation to focus exclusively on pharmacogenomics. NorthShore, with three hospitals in the very first group to achieve Stage 7 on the HIMSS Analytics EMR Adoption Model, has long been nearly paperless. Mark Dunnenberger, senior clinical specialist in pharmacogenomics in NorthShore's Center for Molecular Medicine, envisions a future where every NorthShore patient will have pharmacogenomic data in their medical records. With this goal in mind, he and his team must figure out how to get pharmacogenomic issues into medical records so physicians can use it in practice. Dunnenberger says his team is working on building "systematic and discrete data points" into the medical record to make this information easily accessible to clinicians and compatible with clinical decision support systems. "It will be like doing drug–drug and drug–allergy checks," according to Dunnenberger. The Clinical Pharmacogenomics Implementation Consortium, supported by NIH and run by St. Jude Children's Research Hospital, is driving the development of such data points.

Trial of Everolimus-Eluting Stents or Bypass Surgery for Coronary Disease
New England Journal of Medicine (03/26/15) Vol. 372, No. 13, P. 12; Park, Saung-Jung; Ahn, Jung-Min; Kim, Young-Hak

Researchers for the BEST Trial report that for patients with multivessel coronary artery disease, those who had undergone percutaneous coronary intervention (PCI) with everolimus-eluting stents had a higher rate of major adverse cardiovascular events than patients who had undergone coronary-artery bypass grafting (CABG). The study, which had planned to include more than 1,700 patients at 27 centers in East Asia, was stopped early due to slow enrollment. Of the 880 patients enrolled, the primary endpoint—a composite of death, myocardial infarction (MI), or target-vessel revascularization at 2 years—occurred in 11% of the PCI group and in 7.9% of the CABG group. At a median follow-up of 4.6 years, the primary endpoint had occurred in 15.3% of the PCI patients and in 10.6% of the CABG patients. There were no significant differences between the PCI and CABG groups in terms of a composite safety endpoint of death, MI, or stroke, but rates of any repeat revascularization and spontaneous MI were significantly higher following PCI than after CABG, according to the findings.

ASHP, ISMP Issue Warning About Look-Alike Packaging for Neostigmine and Phenylephrine
American Society of Health-System Pharmacists (03/24/15)

The American Society of Health-System Pharmacists and the Institute for Safe Medication Practices have issued a National Alert for Serious Medication Errors regarding look-alike packaging for neostigmine injection (Bloxiverz—Eclat) and phenylephrine injection (Vazculep—Eclat). Neostigmine is a cholinesterase inhibitor indicated for the reversal of nondepolarizing neuromuscular blockade after surgery, while phenylephrine is approved for the treatment of clinically important hypotension resulting primarily for vasodilation in an anesthesia setting. Health care providers have reported concerns about similarities in the size, color, and design of the vials and outer cartons of neostigmine injection 10 mg per 10 mL and phenylephrine 50 mg per 5 mL. There have been storage mix-ups as well as several close calls in which the wrong product was used during sterile compounding. To safeguard against further mix-ups, ASHP and ISMP recommend keeping supplies of the drugs widely separated in long- and short-term storage areas; alerting staff to the potential risk for confusion between the drugs; bar code scanning containers during inventory management and before dispensing; and diluting phenylephrine injection prior to administration.

Definitions of Pharmaceutical Opioid Use Disorders and Dependence for Chronic Pain
The Lancet Psychiatry (03/18/15) Degenhardt, Louisa; Bruno, Raimondo; Lintzeris, Nicholas

A study was conducted to compare the World Health Organization's ICD-10 and proposed ICD-11 and the American Psychiatric Association's DSM-IV and DSM-5 classifications for opioid use disorders. Researchers examined similarities between classification systems and tested the unidimensionality of the syndrome. The study, which included more than 1,400 patients taking prescription opioids for chronic pain, found that the proportion of participants fitting the criteria for lifetime dependence was generally congruent between DSM-IV, ICD-10, and ICD-11. The researchers concluded that the ICD-11 definition of dependence was not only the best fit but also the most analogous with previous classification systems.

Afblibercept, Bevacizumab, or Ranibizumab for DME

In a study of 660 adults, researchers tested the relative efficacy and safety of intravitreous afblibercept (Eylea—Regeneron), bevacizumab (Avastin—Genentech), and ranibizumab (Lucentis—Genentech) in treating diabetic macular edema (DME). Patients were randomly assigned to receive 2 mg intravitreous afblibercept, 1.25 mg bevacizumab, or 0.3 mg ranibizumab. Medications were administered as often as every 4 weeks for 1 year. Between baseline and 1 year, the mean visual-acuity letter score improved by 13.3 with afblibercept, by 9.7 with bevacizumab, and by 11.2 with ranibizumab. While improvement was greater with afblibercept, it was not clinically meaningful, as the difference was driven by the eyes with worse visual acuity at baseline. Researchers found no significant differences in rates of serious adverse events, hospitalization, death, or major cardiovascular events. All three treatments improved vision in eyes with center-involved DME, but the relative effect depended on baseline visual acuity.
FDA’s Electronic Drug Labeling Proposal Comes Under Fire
Regulatory Affairs Professionals Society (03/25/2015) Gaffney, Alexander

Legislators and patient safety groups warn that FDA’s effort to require certain drug labeling information to be distributed electronically instead of on paper “package inserts” could put patients at risk. The proposed regulation would bar drug manufacturers from distributing information in paper form, in order to “ensure that the most current prescribing information for prescription drugs will be available and readily accessible to health care professionals at the time of clinical decision-making and dispensing.” The electronic requirements do not apply to patient labeling, including package inserts and medication guides, or promotional labeling—only to the drug’s “professional labeling.” Some safety groups have called the proposal unworkable in its current format, complaining that the label repository website is onerous to use. Meanwhile, several legislators have written to FDA expressing their concern about the proposed rule. “Pharmaceutical paper inserts are an important tool for our pharmacists and health care professionals that are in charge of administering life-saving medications to our hardworking families and seniors,” said Sens. Susan Collins (R-ME), Angus King (I-ME), and Rep. Bruce Poliquin (R-ME) in a joint statement.

Sagent Recalls Atracurium Besylate Injection
FDA MedWatch (02/24/15)

Sagent Pharmaceuticals has initiated a voluntary recall of two lots of atracurium besylate injection, USP, 50 mg/5mL single-dose vials (NDC 25021-659-05) and four lots of atracurium besylate injection, USP, 100 mg/10mL multi-dose vials (NDC 25021-672-10) made by Emcure Pharmaceuticals Ltd. and distributed by Sagent. The recall is being undertaken due to FDA observations related to aseptic and GMP practices at the manufacturer’s site that could potentially affect product sterility. The recalled lot numbers are VATA012, VATA015 (50 mg/5mL) and VATB012, VATB013, VATB014, VATB017 (100 mg/10mL). These were distributed to hospitals, wholesalers, and distributors nationwide from February 2014 through February 2015. Sagent reports that it has transferred the manufacture of the drug to its own facility, and the product manufactured there is not involved in the recall.

Are New Oral Anticoagulant Dosing Recommendations Optimal for All Patients?
Journal of the American Medical Association (03/10/15) Vol. 313, No. 10, P. 1013; Powell, J. Robert

A Viewpoint article discusses optimal dosing of new oral anticoagulant drugs for all patients. J. Robert Powell, PharmD, Eshelman School of Pharmacy, University of North Carolina, points out that research has shown the new direct-acting oral anticoagulants (DOACs) to be noninferior or superior to individualized warfarin dosing for preventing stroke, with a similar or lower risk of hemorrhage. There are several common features to these drugs, but individualized dosing could further increase patient safety. Powell suggests that individualized DOAC dosing could be useful for drugs with greater interpatient variability in pharmacokinetics or pharmacodynamics, patients who do not have average characteristics, or when patients have multiple characteristics that could affect dosing. However, without FDA action on the issue, drug companies likely will not move in this direction. “It may be that dose individualization could decrease differences between drugs if they are titrated to a more common standard based on individual patient requirements,” writes Powell. “Greater assurance is needed so these new anticoagulants can be optimally dosed for all eligible patients.”

Technology Helps Yuma Pharmacists Help Patients
Pharmacy Practice News (03/19/15) Rosenthal, Marie

Yuma Regional Medical Center (YRMC) appears to be a nondescript hospital nestled in a remote corner of Arizona, 20 miles north of the U.S.-Mexico border and 180 miles clear of the nearest U.S. acute care hospital. But YRMC is more than just a run-of-the-mill medical facility, as evidenced by its use of automation technology to better serve the community, decrease medication errors, increase patient safety, and support the doctors and nurses. The centerpiece is an integrated automation solution by Aesynt. A physician inputs an order, the pharmacist verifies it, and a robot fills the order. The robot repackages the tablets into single-dose units and marks them; so far, it has completed more than 40 million doses and has yet to make an error. For a rural hospital, such precise inventory control is particularly important because help following a stocking error is nowhere close. In addition, the investment in automation technology shows a commitment to devoting less time to paperwork and more time to personalized patient care.