Pharmacy News

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Special Points of Interest:

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- Policy and Procedures Update
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- Revised GOLD Guidelines for the Treatment of Chronic Obstructive Pulmonary Disease
- Statin therapy and the Associated Risk of Diabetes

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P&T Update

Formulary Additions

Nivolumab (Opdivo®) - formulary addition – Approved

- Nivolumab is a human immunoglobulin G4 (IgG4) monoclonal antibody that binds to PD-1 receptors preventing interaction with PD-L1 and PD-L2. It's used as a 2nd line agent for a number of oncology indications including Malignant Melanoma, Non-Small Cell Lung Cancer, Hodgkin's Lymphoma, Renal Cell Carcinoma, and Squamous Cell Carcinoma of the Head or Neck

Polyethylene glycol 3350 (Miralax®) line extension addition – Approved

- Pharmacy proposed line extension consideration for polyethylene glycol 3350 (MiraLAX®) addition. Product has been used on a non-formulary status for years. Class review of laxatives was presented. Currently, UH Formulary includes glycerin suppositories, lactulose and polyethylene glycol-electrolyte (Golytely®) in osmotic action class. Members support this line extension, citing in pediatric population, glycerin only acts on the colon, in certain cases, option of MiraLAX® to act in small intestine & colon after glycerin trial is needed. Laxative class review:

	Product	Formulary	Adult Dose	Onset of Action	Site of Action	Mechanism of Action	In-patient $/ dose
Osmotic Laxatives	Polyethylene glycol 3350	N	17g/120-240mL daily	48 hrs	Small & large intestine	Nonabsorbable soln which acts as an osmotic agent	$0.76 / 17g
	Polyethylene glycol-electrolyte	Y	PO: 240mL q10min x 4L NGT: 240mL q20-30 min	48 hrs			$7.21 / 4L
	Glycerin sup	Y	1 supp daily prn	15-30 min	Colon	Local irritation, hyperosmotic action	$0.04 / 2G
	Lactulose	Y	10-20g daily max 40g Portal systemic enceph: 20-30g tid-qid Overt hepatic encephal: 16.7g q1-2h until 2 BM	24-48 hrs	Colon	Delivers osmotically active molecules to colon	$0.41 / 30mL (20g)
	Sodium sulfate K+ sulfate Mg++ sulfate	N		24 hrs	Small & large intestine	Hyperosmotic action	
	Sorbitol 70%	Y	PO: 30-150mL x 1 Enema: 120mL x 1	24-48 hrs	Colon	Delivers osmotically active molecules to colon	$0.89 / 30mL
Saline	Mg++ citrate Mg++ hydroxide	Y Y	195mL -300mL x 1 2.4-4.8g (30-60mL) hs	30 min - 3 hrs	Small & large intestine	Attract/retain water in intestinal lumen increasing intraluminal pressure; cholecystokinin release	$1.53 / 296mL $0.99 / 30mL
	Na+ phosphates	N		2-15 min	Colon		$1.03 / 133mL
Irritant/stimulant	Senna	Y	10-15mL/qd max 15ml bid 17.2mg(2)/day max 4 bid	6-10 hrs	Colon	Direct action on intestinal mucosa; stimulate mesenteric plexus; alter water and electrolyte secretion	$0.07 / 8.6mg Tab $1.49 / 5mL liqu
	Bisacodyl	Y	PO: 5-15mg daily Sup: 10mg daily	15-60 min	Colon		$0.26 / 5mg Tab $0.06 / 10mg supp
	Castor oil	N	15-60mL x 1	1-3 hrs	Small intestine		
Bulk producing	Methylcellulose Psyllium Wheat dextrin	N Y N	2g/8oz tid, 2cap 6x/day 2.5-30g/day divided M: 38g/day, F: 25g/day	12-24h 24-48h	Small & large intestine	Holds water in stool; mechanical distention	$5.85 / 454 Gm $0.32 / 3.4 Gm pkt
Lubricant	Mineral oil	Y	PO: 15-45mL/24h max45 PR: 118mL x 1	6-8 hrs	Colon	Lubricates intestine; retards colonic absorption of fecal water; softens stool	
Stool softner	Docusate sodium Docusate calcium	Y	50-360mg/day divided 240mg daily	24-72 hrs	Small & large intestine	Detergent activity; facilitates admixture of fat and water to soften stool	$0.03 / 100mg cap
Opiod-induced	Alvimopan	N	Initial: 12mg 30m-5h pre-op Maint 12mg bid max 7 days	Unknown	GI tract mu-opioid receptors	Blocks mu-opioid receptors in GI tract, thereby antagonizing the constipating effects of opioids; restricted ability to cross the BBB	CAP:
	Methylnaltrexone	N	Non-CA: PO 450mg/day Subcut: 12mg/day	30-60 min	Peripheral mu-opioid receptors, including the GI tract	Blocks peripheral mu-opioid receptors, thereby antagonizing the constipating effects of opioids; limited ability to cross the BBB	$16.10 / 150mg T $48.30 / 450mg T $96.58 / 12mg inj
	Naloxegol	N	PO: 25mg qam, may reduce to 12.5mg	6-12 hrs			$9.4 / 25mg tab $9.4 / 12.5mg tab

Formulary Deletions

Meningococcal polysaccharide vaccine (Menomune®) deletion – Approved

- Manufacturer (Sanofi Pasteur) has decided to discontinue the production of Menomune®. Formulary deletion proposed. UH currently have Menveo® as ACIP recommended off label alternative to Menomune® for meningococcal vaccine.

Policies & Procedures/Floor Stock Update

1. **707-500-110 High Risk High Alert/Look Alike Sound Alike Medication Policy Revision**
   Following Medication Safety Committee review and approval of eliminating the RN double sign for MAR actions on lookalike sound alike and epidural/intrathecal medication, revisions are made in the policy to accurately reflect new practice of single sign for the affected medications.

2. **707-700-106 Who May Administer Medication Policy Revision**
   Following Medication Safety Committee review and approval of eliminating the RN double sign for MAR actions on lookalike sound alike and epidural/intrathecal medication, revisions are made in the policy to accurately reflect new practice of single sign for the affected medications.

3. **707-700-114 Epidural Anesthesia Policy Revision**
   Following Medication Safety Committee review and approval of eliminating the RN double sign for MAR actions on lookalike sound alike and epidural/intrathecal medication, revisions are made in the policy to accurately reflect new practice of single sign for the affected medications.

4. **707-700-101 Administering & Charting Medications to Patients Policy Revision**
   Two policies both focusing on medication administration and charting administrations in EPIC were combined. This policy includes all aspects of current medication administration practices, including BCMA and Carpuject usage.

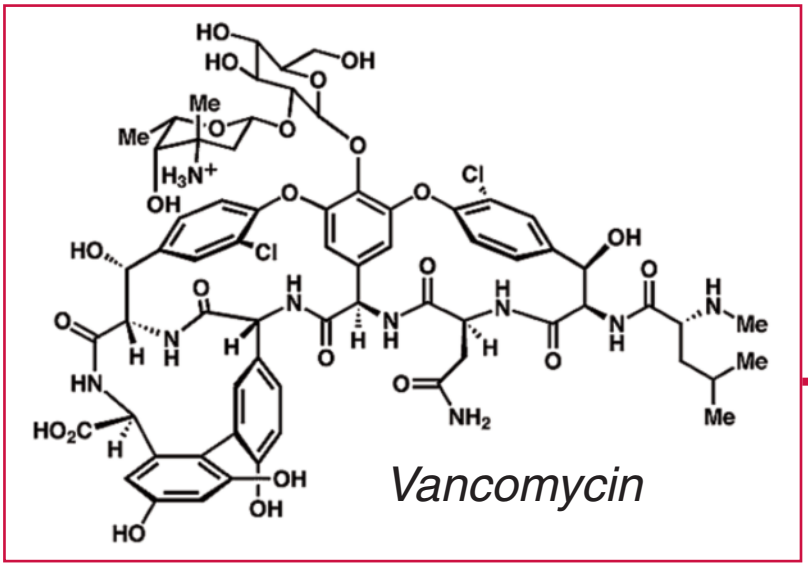
5. **5-Fluorouracil (5-FU) overdose/toxicity Policy – Approved**
   A new Policy and Guideline for patients determined to have a 5-FU overdose was developed and endorsed by the oncology subcommittee. Policy dictates the oncologist on-call should be paged as soon as an overdose is identified, and an action plan is outlined depending on the severity of the overdose.

6. **UH Pharmacy policy & procedure table of content for 2017 approval – Approved**
   List of Pharmacy Policy and Procedures were presented for 2017 approval. Pharmacy Policies and Procedures: 184
   Protocols & guidelines: 7
   Dangerous abbreviation List
   Look alike, sound alike, high risk, high alert medication list

7. **5-Fluorouracil (5-FU) overdose/ toxicity new policy – Approved**
   A new Policy & Guideline for patients with 5-FU overdose was developed by the oncology subcommittee Policy dictates the oncologist on-call should be paged as soon as an overdose is identified, and an action plan is outlined depending on the severity of the overdose.

The progression of Treatment in Severe *Clostridium difficile*

The Centers for Disease Control and Prevention reported nearly half a million infections due to *Clostridium difficile* among patients in 2016. Clostridium difficile infection (CDI) may be classified as mild, moderate or severe depending upon symptoms. Any classification of CDI is recognizably dangerous with warranted prompt treatment, however, a major concern lays in treatment of severe CDI (patients with white blood cell count >15k or serum creatinine >1.5x baseline) due to the likely possibility of fatality. The greater mortality associated with severe CDI places a dependence on guidelines for updated information as they ultimately define treatment for infection of *Clostridium difficile* [1].



To date there are five published guidelines for the treatment of CDI: Society for Healthcare Epidemiology of America/ Infectious Disease Society of America (SHEA/IDSA), American College of Gastroenterology (ACC), European Society of Clinical Microbiology & Infectious Diseases (ESMID), World Society of Emergency Surgery (WSES), and Australasian Society for Infectious Disease. Guidelines have been published over the last seven years with Australasian being most current. All guidelines recognized metronidazole or vancomycin as appropriate treatment for CDI with vancomycin being first line for treatment of severe CDI. SHEA/IDSA (2010) and ACC (2013) provided a strong recommendation for first line vancomycin treatment in severe CDI, but with moderate quality evidence as support, meaning further strong research is likely to have an impact in the recommendation. The backing of SHEA/IDSA recommendation with moderate quality evidence has made vancomycin initiation for severe CDI less likely [3]. On the other hand, ESMID (2014), WSES (2015), and Australasian (2016) provided a strong recommendation with high quality evidence for first line vancomycin treatment in severe CDI. The discrepancy in information amongst guidelines is solely attributable to the laggard update following publication of significant studies, which may impact or change current recommendations.

Since the publication of SHEA/IDSA in 2010, additional clinical trials and studies have been carried out to strengthen the recommendation of vancomycin as first line treatment in severe CDI, which are reflected in more recent guidelines. The change in recommendation with subsequent guidelines demonstrates a progression in vancomycin superiority to metronidazole in severe CDI. Recently published cohort studies further build on the existing evidence of vancomycin superiority in treatment of severe CDI over metronidazole.

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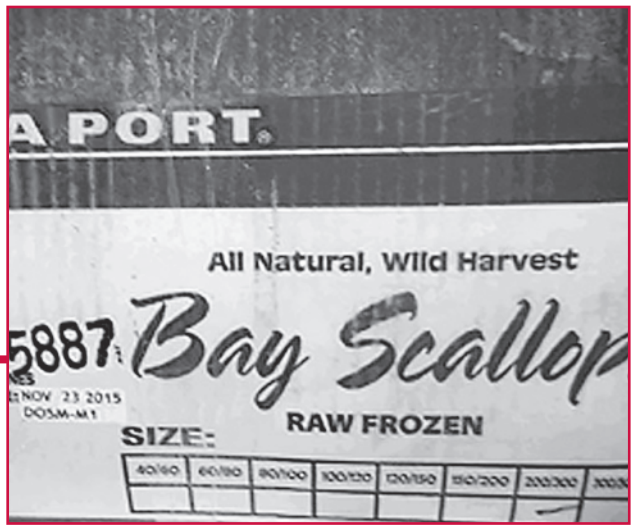
FDA Investigates Outbreak of Hepatitis A Illnesses Linked to Raw Scallops

Hepatitis A is a contagious liver disease resulting from infection with Hepatitis A virus (HAV). The disease ranges in severity from mild illness that lasts a couple of weeks to severe symptoms that can last up to several months. Hepatitis A spreads when a person ingests fecal matter through contact with food, drinks, or objects contaminated by feces of an



infected person. Symptoms of the disease include fatigue, abdominal pain, jaundice, abnormal liver tests, dark urine, and pale stool. People at risk for developing Hepatitis A are the following: pregnant women, young children, elderly, individuals who are immunocompromised, have decreased stomach acidity or liver dysfunction. Therefore, people who have underlying liver conditions or other preexisting conditions should be vaccinated for HAV.

In a recent finding, the FDA and CDC worked with the Hawaii department of health (DOH) to investigate an outbreak of Hepatitis A linked to consuming raw scallops.The FDA did a traceback investigation where they would try to see where the scallops were sourced from. The investigation determined that Sea Port Products Corp imported the scallops that were later given to sushi restaurants in Hawaii where sick people reported eating. On August 17, 2016, the FDA did laboratory analysis on two scallop samples that had confirmed positive results for Hepatitis A. The samples were imported by Sea Port Products Corp and were made on November 23rd, 2015. The FDA, CDC, and Hawaii DOH informed Sea Port Products Corp that their scallops were the likely cause of the illnesses. On August 18, 2016, Sea Port Products Corp voluntarily recalled 3 lots of frozen Bay Scallops made on November 23rd and 24th of 2015. The lot numbers were 5885, 5886, and 5887. These recalled products were distributed originally to California, Hawaii, and Nevada. Sea Ports Products Corp stated that the recalled products were not intended for retail sale. The FDA worked closely with the recall group to makes sure the recall process was efficient and that the products were removed from the market.

To combat this recent outbreak case, the FDA has a list on selecting and serving fresh and frozen sea food safely. There are recommendations included for restaurants and retailers as well as for consumers in practicing seafood safety. For restaurant and retailers, they should wash and sanitize areas such as refrigerators that store potentially contaminated products. They should also wash all cutting boards, surfaces, and utensils to prevent potential contamination. Employees should also focus on watching hands efficiently with warm soap and water. Consumers should also make sure to wash hands properly after using the bathroom to prevent the spread of diseases such as Hepatitis A. By taking the appropriate steps in practicing proper hygiene and cleanliness, individuals can contribute to the efforts in preventing future outbreaks from occurring.

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Role of Clonidine in Treating Neonatal Abstinence Syndrome

Infants could experience withdrawal symptoms after abrupt discontinuation of opioids which they were exposed to. This condition is called "Neonatal abstinence syndrome" (NAS). The major symptoms of this condition are irritability, hypertonia, failure to gain weight, poor sucking reflex, autonomic instability. According to Tolia et al[3], the admission rate for NAS has increased from 2004 to 2009. Low socioeconomic status and education level and genetic predisposition are some of the factors that may explain the increasing incidence of NAS in hospital. There are effective treatments for opioid overdose such as Methadone; however its use may be one of the reasons that NAS is increasing.

Clonidine is an interesting drug for treating NAS. The NAS affects multiple body systems by changing the balance of neurotransmitter (such as serotonin, noradrenaline, dopamine, acetylcholine, corticotropin) levels. There are two modes of treatment for NAS; Nonpharmacological and Pharmacological. According to American academy of Pediatrics (AAP) opioids are the first-line agents for treating NAS. One of the new and safe pharmacological approaches is to treat with Clonidine. This drug works by stimulating the alpha2-autoreceptors in the brain and resulting in decreasing sympathetic outflow caused by over-excited mureceptors. Clonidine is eliminated by kidney and its clearance depends on the renal function of the child. It clears at a slower rate as the child matures. It has a good safety profile and its effect on Blood pressure has been shown to be clinically insignificant and it doesn't have cardiovascular side effects. Clonidine is a good alternative to other therapies such as Phenobarbital. It doesn't cause respiratory depression as phenobarbital. It is most commonly formulated as oral. Clonidine is also used as an adjuvant agent for treating and shortening the treatment duration of NAS. According to Broome[2], "A target plasma concentration of 0.8-1.0 ng/mL was confirmed by previous studies to provide adequate sedation in pediatric patients ages 1-11 years". If after reaching the target concentration the patient is still experiencing NAS symptoms, an alternative agent should be used rather than increasing the dose. Additional clinical studies are required to optimize the dosing strategy.

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Revised GOLD Guidelines for the Treatment of Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable and treatable disease characterized by persistent respiratory symptoms and airflow limitation. These limitations are due to airway and/or alveolar abnormalities caused by significant exposure to noxious particles such as cigarette smoke. COPD is currently the third leading cause of death in the United States and the fourth leading cause of death globally. The revised Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines were published in February to further improve the quality of COPD understanding and treatment.

The revised GOLD guidelines state that a confirmed diagnosis of COPD requires the ratio $FEV^1/FVC < 0.7$ to indicate persistent airflow limitations. FEV^1 is used to assess the severity of airflow limitation and classifies patients as GOLD 1 (mild) to 4 (severe). It is also necessary to assess the severity of symptoms by using the Modified British Medical Research Council (mMRC) questionnaire for breathlessness or the COPD Assessment Test (CAT) which gives a comprehensive assessment of symptoms such as cough, chest tightness, and sputum production. Symptoms and exacerbation history are used to classify patients into groups A-D. Groups are used to determine pharmacological treatment.

Treatment recommendations for an acute COPD exacerbation include the use of short acting beta2-agonists with or without short-acting anticholinergics, systemic corticosteroids for a duration of 5-7 days, and when indicated, antibiotics may also be used for 5-7 days. The use of systemic corticosteroids and antibiotics are shown to reduce the duration of recovery/hospitalization. Methylxanthines are not recommended for exacerbations as they require near toxic doses to be effective. Non-invasive ventilation (NIV) is recommended over invasive ventilation for the treatment of acute respiratory failure in hospitalized patients because it has been shown to decrease morbidity and mortality.

Cigarette smoking is one of the main risk factors for COPD. Smoking cessation has become a primary goal for patients at risk for COPD. Since COPD is preventable and treatable, but not curable, prevention of disease progression is essential. In addition, the updated guidelines recommend that patients with COPD receive the influenza and pneumococcal vaccines to prevent lower respiratory tract infections. It is recommended that patients be screened for alpha-1 antitrypsin deficiency because although it is not common, it plays a role in COPD and patients may benefit from augmentation therapy. Although treatment options continue to improve, prevention and early treatment remain the top priorities in reducing the prevalence of COPD and the risk of exacerbations.

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Statin Therapy and the Associated Risk of Diabetes

On May 25, 2017, a California U.S. District Judge upheld a ruling that will allow a group of women to litigate their claim that Pfizer's statin lowering medication, Lipitor, caused in their diabetes. The block-buster medication once brought in $9.58 billion in global sales for Pfizer in 2011 and those sales have since diminished to $1.7 billion around the world last year.[1] The pharmaceutical giant is now defending against these claims in court.

In the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) trial, with 4731 patients, 2365 patients were treated with Lipitor 80mg pharmacotherapy and 2366 patients were given a placebo for a approximately 4.9 years. In this trial, "diabetes was reported as an adverse event in 144 subjects (6.1%) in the atorvastatin group and 89 subjects (3.8%) in the placebo group."[2]

In a comparative meta-analysis conducted by Sattar et. al., published in the Lancet in February 2010, 13 statin random clinical trials were reviewed. The results from the meta-analysis illustrated that statin therapy was associated with a "9% increase in the incidence of diabetes (odds ratio [OR] 1.09; 95% CI 1.02-1.17), with little heterogeneity (I(2)=11%)."[3] This risk was observed to be the greatest in the older population.

In a consumer update published on February 16, 2017, the FDA acknowledged the claim that the one of the major risks that patient's on statin therapy should be cautious about are an increased risk of developing type 2 diabetes. However, James P. Smith, M.D., M.S., and deputy director of the Division of Metabolism and Endocrinology at the U.S. Food and Drug Administration (FDA), clarified that the importance of statin therapy. He states, "The benefits of statins in reducing heart attacks and strokes should generally outweigh this small increased risk."[4]

Current data may suggest that diabetes is a caution for statin therapy. However, data from the metaanalysis conducted by Sattar et. al., illustrates that 255 subjects over 4 years will cause one new case of diabetes. The authors from this meta-analysis and the FDA deputy director advised that clinical practice should not be changed based on these findings as the benefits of statin therapy outweigh the associated risk.

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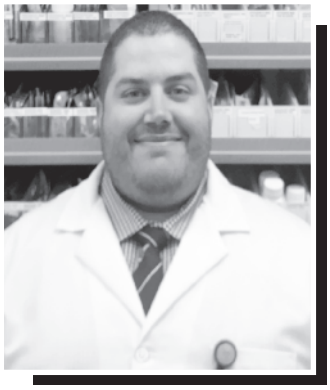
Welcome New Pharmacists

Merit Henen

Dr. Merit Henen received her Doctor of Pharmacy degree from Long Island University in Brooklyn, New York in 2013. She worked in a retail pharmacy both during school and after graduation, before deciding to change her area of practice to diversify her experience. She pursued a staff pharmacist position at University Hospital to expand her knowledge of pharmacy, always trying to learn new things. During her free time she enjoys going out with friends, spending time with her family, and traveling.



Jason M. Donnelly, Pharm D.

Dr. Jason Donnelly earned his Doctor of Pharmacy degree from the Massachusetts College of Pharmacy and Allied Health Sciences (MCPHS) in Boston, in 2010. After graduating, Jason worked in retail pharmacy for seven years as the Pharmacy Manager in multiple locations before being hired by University Hospital. In his free time, Jason enjoys spending time with his family, playing golf and watching a variety of sports.

Peter Ibrahim

Peter Ibrahim, graduated Mansoura pharmacy school - Egypt 2011. He is joining uhnj with great passion . He Always wants to take care of our patients. Clinical researching is his reason that encourages him to join our team at uhnj. Looking forward to escalate and develop his clinical skills at UHNJ.

Srujal Patel, Pharm.D., BCPS.

Dr. Srujal Patel earned her Doctor of Pharmacy degree from Long Island University School of Pharmacy in Brooklyn in 2007. During her clinical rotations, she explored a variety of careers within pharmacy. After graduation, she worked at long term care pharmacy and at an independent community pharmacy. She got her board certification in pharmacotherapy specialist in 2015 to advance her career. She is excited to work at the University Hospital. This opportunity will fulfill her dream to advance her career and to provide better patient care. She enjoys spending time with her family, traveling, cooking, running and swimming.