SCHOOL OF PHARMACY
UNIVERSITY of WASHINGTON

The Resident Star

By The University of Washington Community Pharmacy Residents

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Inside this issue:

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Drug Information

New option for COPD: Umeclidinium/Vilanterol (Anoro Ellipta)

By John Doric, PharmD (Providence Pharmacy Monroe)

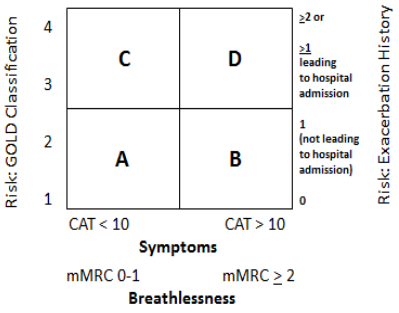
Moderate to Severe COPD standard of care utilizes inhaled anticholinergic, inhaled corticosteroids, and long acting beta-agonists to achieve appropriate outcomes of reduced exacerbations as well as reduced symptoms such as dyspnea, cough and sputum production.

Updated GOLD guidelines for COPD outline and focus on spirometric as well as symptomatic changes in staging and drug recommendations. This includes tailoring therapy for exacerbations (adding ICS), or adding on a longer acting anticholinergic/beta agonist (LAAC/LABA) for decreases in FEV1 or increased symptoms and/or breathlessness.

Table 2.5. Classification of Severity of Airflow Limitation in COPD (Based on Post-Bronchodilator FEV_1)

In patients with $FEV_1/FVC < 0.70$:		
GOLD 1:	Mild	$FEV_1 \geq 80\%$ predicted
GOLD 2:	Moderate	$50\% \leq FEV_1 < 80\%$ predicted
GOLD 3:	Severe	$30\% \leq FEV_1 < 50\%$ predicted
GOLD 4:	Very Severe	$FEV_1 < 30\%$ predicted

COPD: Staging



Pharmacological Management of COPD		
Patient Group	**Recommended First Choice**	**Alternative**
A	SAAC prn or SABA prn	LAAC or LABA or SABA and SAAC
B	LAAC or LABA	LAAC and LABA
C	ICS and LABA or LAAC	LAAC and LABA or LAAC and PDE-4 inhibitor or LABA and PDE-4 inhibitor
D	ICS and LABA and/or LAAC	ICS and LABA and LAAC or ICS and LABA and PDE-4 inhibitor or LAAC and LABA or LAAC and PDE-4 inhibitor

	Duration of action (Hours)
Long acting beta2-agonist	
Salmeterol	12
Formoterol	12
Indacaterol	24
Long acting anticholinergic	
Tiotropium	24
Combination LABA and LAAC	
Umeclidinium/Vilanterol	24

Options for LABAs as well as LAACs were not previously available as a combination product, thus restricting patients to use multiple inhalers, which increases cost and causes compliance issues. In addition, most commonly used LABAs are dosed twice daily as a singular product.

Anoro Ellipta is a new option that allows for convenient once daily dosing for LABA/LAAC therapy in patients with moderate to severe COPD, with the option of adding on a separate ICS in those patients with exacerbation history/hospital admission history.

References:

1. From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015. Available from: http://www.goldcopd.org/

2. Package insert product information: ANORO(TM) ELLIPTA(TM) oral inhalation powder, umeclidinium vilanterol oral inhalation powder. GlaxoSmithKline

Drug Information

Two New Vaccines for Meningococcal Hit the Market

By Mark Amoo (Bartell Drugs)

Mark Amoo, PharmD

Bacterial meningitis caused by Neisseria meningitidis is a serious infection that has entered the forefront of public attention due to 2 college campus outbreaks in 2013 of the serogroup B type. Meningitis is an inflammatory disease which affects the tissues surrounding the brain and spinal cord, potentially leading to hearing loss, neurological damage, or loss of limb. This highly fatal disease is preventable due to the availability of vaccines, such as Menveo and Menactra, which have been available for decades. However, with 4 of 5 known N. meningitidis serogroups (A, C,W, and Y) only being covered by these current vaccines, the swift FDA approval of two new vaccines for serogroup B coverage into US market comes during a time when the need to prevent more outbreaks is urgent.

Trumenba (Pfizer, FDA approved 10/2014) and Bexsero (Novartis, FDA approved 1/2015) are both indicated for individuals 10 to 25 years of age. Both have been shown to confer immunogenicity against N. meningitidis serogroup B through a scheduled series of intramuscular injections over a period of time. These vaccines have a similar side effect profile with injection site pain being the most common complaint among study subjects. However, the long-term immunogenicity of either vaccine is still questionable with Trumenba lacking any data as of yet, and reports of immunity conferred by Bexsero waning by 5-25% after two years.

Trumenba confers immunity to 4-strains of serogroup B via factor H binding protein (FHbp) types B and A variants, antigens found on all strains of serogroup B. Stored in prefilled syringes, a 0.5-mL dose is administered IM into the deltoid at scheduled time points 0-, 2-, and 6-months. Major side effects being fatigue, headaches, and muscle pain. A single dose per McKesson may be priced around $115 without administration costs.

Bexsero confers immunity to 3-strains of serogroup B via FHbp variant B, NhbA, NadA, and Por A1.4 vaccine antigen components. A 0.5-mL dose is administered IM into the deltoid muscle in 2 doses separated by a minimum 1-month period. Major side effects included headache, induration at injection site, and erythema. While most subjects for Bexsero trials originate from outside the United States and may not be representative of the US population, it is has been used much more widely on a global scale, being on the European, Canadian, and Australian markets for years before the release of Trumenba. Cost for administration of Bexsero in the US is not available as of yet, but the cost of a 2-dose series outside the US ranges anywhere from $500 to $925.

Drug Information (continued)

Two New Vaccines for Meningococcal Hit the Market

By Mark Amoo (Bartell Drugs)

ACIP currently recommends vaccination of adolescence age 11 through 18 years and patients with compromised immune systems to be vaccinated for serogroups A, C, W, and Y. However, ACIP has yet to determine guidelines or recommendations regarding serogroup B vaccination. There are planned meetings to assess High Risk groups and to review evidence for expanded target groups for vaccine administration. Overall, both vaccines have been found to be safe and effective by their respective manufacturers, however more studies need to be performed to assess the long-term efficacy and recommending either should be done after a thorough evaluation of their risk of exposure, in conjunction with the patient and their physician.

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1. Novartis Vaccines and Diagnostics, Inc. (2015). Bexsero: Highlights of Prescribing Information. Cambridge, MA.
2. Wyeth Pharmaceuticals Inc (2014). Trumenba: Highlights of Prescribing Information. Philidelphia, PA.
3. Patel, Manisha. 'Overview Of Serogroup B Meningococcal Vaccines And Considerations For Use'. CDC Advisory Committee on Immunization Practices (ACIP), 2014. Presentation.
4. Cohn AC, MacNeil JR, Clark TA, Ortega-Sanchez IR, Briere EZ, Meissner HC, Baker CJ, Messonnier NE; Centers for Disease Control and Prevention (CDC). Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2013 Mar 22;62(RR-2):1-28.
5. Wheeler, C (2015 February 15). Meningitis vaccine delay could see hundreds of Brits die. Daily Express. Retrieved from http://www.express.co.uk/news/uk/558240/Meningitis-vaccine-delay-government
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Clinical Service

American Heart Month at Bartell Drugs

By Mark Amoo (Bartell Drugs)

Mark Amoo, PharmD

Last month was American Heart Month at Bartell Drugs and to show our support of heart health we offered our customers a complimentary cholesterol screening. We ran the promotion for the month of February and if customers spent $25 they were able to redeem a complimentary voucher for a full lipid panel. Guests were encouraged to fast before coming in for their screening and could schedule appointments online. The pharmacist who performed the exam discussed patient handouts with the customer on the importance of cholesterol and heart health as well as how to achieve and/or maintain healthy levels. Results were also faxed to the customer's primary care physician so that they could be followed up with appropriately.

Bartell Drugs' pharmacist are able to provide cholesterol screens as point of care testing in the community pharmacy setting because the device we use (CardioChek) is CLIA waived. American Heart Month was a huge success at Bartell Drugs because not only were we able to provide our customers with a free screening service but we were also able to help raise public awareness on the clinical services that all pharmacists can provide.

Clinical Service

Therapeutic Substitution

By John Doric, PharmD (Providence Pharmacy Monroe)

John Doric, PharmD

One of the additional clinical services that pharmacists at Providence participate in is therapeutic drug substitution. Our therapeutic substitution protocol is a working part of a collaborative drug therapy agreement within the Monroe clinic. This augments well with other clinic services such as refill authorizations, access to medical records in the outpatient pharmacy, and physically being located near providers for recommendation and discussion. Examples of therapeutic substitutions include inhalers, cardiovascular medications like ACEIs, ARBs, beta blockers, statins, PPIs, H2RAs, allergy medications including nasal corticosteroids and antihistamines, topical antifungals, NSAIDs, oral corticosteroids, triptans, oral estrogens, and topical corticosteroids. Therapeutic substitutions are easily implemented in our pharmacy context when patients have side effects. It also enables the pharmacy to work well with variable purchasing costs and keep a lean inventory. When product availability issues arise, therapeutic substitutions allow for seamless alternative product selections. Overall therapeutic substitution is just one additional way our team offers expanded pharmacist services to our patient population and improves efficiency of our overall clinic workflow.

Clinical Service

UWPC Services for Assisted Living Communities

By Steven Huang, Pharm.D., (UWPC)

Steven Huang, PharmD

As a second year pharmacy resident for UWPC, I am gaining additional experience in caring for older adults. My first year residency had a focus in geriatric care within the home health setting. This year, I am providing non-dispensing pharmacy services to many assisted living communities in the greater Seattle area. Having said that, there have been new challenges working at assisted living communities such as nursing delegation and different levels of care within these communities. Currently, non-dispensing pharmacy services are not common in this type of setting. A lot of what I do besides providing consulting services to the communities is staff education. Healthcare and medication knowledge can vary at these communities where the majority of staff is comprised of medical technicians and nursing assistants who do not have the medical background compared to a licensed practical nurses or registered nurses. Providing in-services and presentations to these groups has been an enlightening experience as to how much medication education from a basic level can improve the quality of care being provided to the residents living at these assisted living communities.

A novel clinical service that is provided to independent living residents at these communities is home visits and walk-in appointments. For one specific community, I have worked with the community relations staff to set up these services so residents can set up either a home visit or walk-in appointment at the pharmacy office. Because of the fact that the large percentage of residents at this community are independent, residents are also free to contact me via email to answer any drug information questions or disease related questions they may have. I am often able to collect additional information after developing rapport with the residents after completing home visits or walk-in appointments. Assessments on medication adherence and psychiatric changes to name a few are very helpful when communicating with their providers.

Drug Information

Geriatric Perspective - Clinical Considerations When Using Statins for Primary Prevention

By Steven Huang, Pharm.D., (UWPC)

Steven Huang, PharmD

Primary prevention of cardiovascular disease (CVD) is important for the elderly. Age is a non-modifiable risk factor for developing CVD. It is reported that about two-thirds of first major coronary events occur in those 65 years of age or older.[1]

However, some clinicians may be hesitant to prescribe statin therapy for primary cardiovascular prevention for older adults.

Some reasons for prescribers being more cautious with using statins in older adults for primary prevention are polypharmacy, cost, and this patient population having a higher risk of experiencing adverse drug reactions. There is also evidence that indicate the older geriatric patient having less clear benefit from statin use and that those 80 years of age or older may actually have a greater risk of overall mortality.[2] There is a hypothesis that some types of LDL may have a protective effect as someone ages.[2] There have been several primary prevention trials that have included patients 60 years of age or older, but currently none have looked at the very elderly patients 80 years of age or older.

Caring for elderly patients has its challenges because one must consider the unique characteristics that require special consideration before starting any new medication. Notable adverse reactions from statins in the elderly population are myopathy and cognitive side effects. Most package inserts for statins state that there are no differences in safety or effectiveness between older and younger adults, however, some package inserts recommend using statins with more caution in the elderly due to advanced age being a predisposing factor for myopathy.[3] Revisions were made in product labeling for statins in 2012 to include information regarding statins effect on cognition stating that "observational studies and clinical trials did not suggest that cognitive changes associate with statin use are common or lead to clinically significant decline."[3] Current guidelines recommend patients on statins who present with confusion or memory impairment be evaluated for other causes in addition to the possibility of experiencing an adverse effect associated with statin therapy.[4]

Risk versus benefit needs to be evaluated on whether or not an older adult should be treated with a statin for primary prevention of CVD. The benefit being a reasonable likelihood of reduction in cardiovascular morbidity or mortality, and the risks being potential for increased cost, pill burden adverse effects, and drug interactions. It is suggested that the benefits should outweigh the risks for statin use in elderly patients without a diagnosis of terminal illness (e.g. cancer, Alzheimer's disease, failure to thrive, etc…) and a life expectancy of at least five years for patients with cardiovascular risk equivalents or multiple risk factors.

Although there are no product-label dosing recommendations for statins in the geriatric patient, pravastatin and atorvastatin are the preferred statins for use in older adults. Pravastatin would be the preferred statin for those on multiple medications because of less risk of cytochrome P450 drug interactions. In addition, it has been studied in the oldest cohort population and was well tolerated in studies. Atorvastatin would be preferred in patients with renal impairment since no adjustments are needed in patients with chronic kidney disease stages 1 through 5.

Table 1. Summary of Statin FDA Product-Label Dosing Recommendations for Renal Impairment

Statin	Moderate renal impairment not on HD	Severe renal impairment not on HD
Fluvastatin	No specific adjustment recommendation	Caution for doses > 40 mg daily (not studied)
Lovastatin	No specific adjustment recommendation	CrCl < 30 mL/min, caution for doses > 20 mg daily
Pravastatin	No specific adjustment recommendation	Starting dose of 10 mg daily
Atorvastatin	No specific adjustment recommendation	No dose adjustment needed
Rosuvastatin	No adjustment needed for CrCl for ≥ 30 mL/min/1.73 m^2	CrCl < 30 mL/min/1.73 m^2 start 5 mg daily and do not exceed 10 mg daily
Simvastatin	No specific adjustment recommendation	Start at 5 mg daily and monitor closely
Pitavastatin	Starting dose 1 mg daily and maximum dose 2 mg daily for CrCl 30 – 59 mL/min/1.73 m^2	Starting dose 1 mg daily and maximum dose 2 mg daily for CrCl 15 – 29 mL/min/1.73 m^2

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3. FDA Drug Safety Communication: important safety label changes to cholesterol-lowering statin drugs. Safety Communication February 28, 2012. Available online at http://www.fda.gov/Drugs/DrugSafety/ucm293101.htm.
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