Blue Ridge Rx

PILL-ANTHROPY POST

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PROBIOTICS: USEFUL OR USELESS?

Rob Holcomb, PharmD Candidate

The efficacy of probiotics, which are live cultures of "helpful" bacterial meant to treat or prevent various gastrointestinal diseases has become a topic of increasing interest for both healthcare providers and patients alike. Probiotics are thought to provide benefit to patients by out-competing harmful bacteria for space and resources in the gut, providing a protective barrier to the gut lining, and/or by enhancing the patient's immune system.

In order for a probiotic to be effective it must first reach the gut. To do this the live cultures of bacteria must be able to survive transit from the manufacturing facility, have an adequate shelf life, and then survive the caustic environment of stomach acids and bile salts encountered in the early GI tract of the patient. For this reason you'll find most probiotics contain large numbers of colony forming units (CFU), often in the billions, and some products have specific storage requirements such as refrigeration.

A recent meta-analysis of 84 randomized controlled trials containing over 10,000 subjects attempted to determine which gastrointestinal conditions may show benefit from the use of various probiotics. Of the 8 gastrointestinal diseases considered, antibiotic associated diarrhea (AAD), infectious diarrhea, irritable bowel syndrome (IBS), H. pylori associated ulcers, C. difficile associated diarrhea (C. diff.) and pouchitis showed statistically significant benefit from the use of probiotics.

The most important factor in the successful use of probiotics is determining the correct product or strains of bacteria for the gastrointestinal disease being treated or prevented. It is also important to note the recommended storage requirements of the probiotics, e.g. some should be refrigerated while others should not. Dosage timing can also play an important role in effective treatment for certain conditions. For example, for the prevention of antibiotic associated diarrhea, many products recommended separating the probiotic dose away from the antibiotic dose by at least 2 hours and to continue the probiotic for one week after the antibiotic course is completed.

Though much work has been done in this exciting new field of research more large scale, well designed studies will be required to determine with certainty which bacterial strains are truly effective and for which gastrointestinal conditions.

References:

1. Ritchie Marina L., Romanuk Tamara N. A Meta-Analysis of Probiotic Efficacy for Gastrointestinal Diseases. PLoS ONE. April 2012.Volume 7:4, e34938.
2. PL Detail-Document, Comparison of Common Probiotic Products. Pharmacist's Letter/Prescriber's Letter. July 2012.

If you have a topic that you would like to see in a future newsletter, please submit it to Dave at dphillips@blueridgerx.com

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES VOTES TO RECOMMEND PREVNAR 13 VACCINE IN ADULTS 65 AND OLDER

Keith Smith, PharmD Candidate

On August 14, the Center for Disease Control's Advisory Committee on Immunization Practices voted to recommend Prevnar 13 (PCV13) for routine use to help prevent pneumococcal disease in adults 65 years and older. Pneumococcal pneumonia is the most common type of community acquired bacterial pneumonia in the United States, affecting approximately 900,000 people each year with a fatality rate of 5 - 7 percent.[1]

Prevnar 13, delivered in a single dose injection, is indicated for active immunization for the prevention of pneumonia and invasive disease caused by 13 strains of *Streptococcus pneumoniae.* The advisory panel took into consideration a clinical trial which included 85,000 patients who received either Prevnar 13 or placebo. Among those treated with Prevnar 13, there were 46 percent fewer first episodes of community-acquired pneumonia than among the placebo group.[2]

Prevnar 13, manufactured by Pfizer, is a tridecavalent vaccine, meaning it contains 13 serotypes of pneumococcus (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F) which are conjugated to a carrier protein. Prevnar 13 was approved by the FDA in 2010 for use in children younger than age 5 and people with compromised immune systems caused by conditions such as cancer, AIDS, and advanced kidney disease.

The Advisory Committee recommended specifically that adults 65 years of age or older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of Pneumovax 23 (PPSV23). Adults 65 years of age or older who have not previously received PCV13 and who have previously received one or more doses of PPSV23 should receive a dose of PCV13.[3]

The recommendations will be forwarded to the director of the CDC and the U.S. Department of Health and Human Services for review and approval. Once approved, the recommendations will be published in the Morbidity and Mortality Weekly Report. Insurance companies will be required to cover the vaccines as part of the 2010 Patient Protection and Affordable Care Act which mandates coverage of vaccines recommended by ACIP. Medicare would immediately cover Prevnar 13; however, the decision whether to cover Pneumovax 23 in patients who had never been immunized could take up to a year.

References:

1. Atkinson W, Wolfe S, Hamborsky J, eds. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 12th ed., second printing. Washington DC: Public Health Foundation, 2012.
2. Kaye, Donald. *Prevnar 13 Prevents Pneumonia in Elderly Adults.* Clinical Infectious Diseases. 2014; 58 (5); i - ii.
3. Pfizer Inc. Press Release. http://www.pfizer.com/news/press-release. Accessed August 22, 2014.

Triad of New Antibiotics to Boost Antimicrobial Arsenal

Keith Smith, PharmD Candidate

Until recently, discovery and development of new antibiotic drugs has been stagnant due to their poor return on investment for pharmaceutical companies. As a result, the rise of antibiotic resistant microorganisms has outpaced the approval of new antimicrobials, leaving physicians with fewer options in their arsenal to treat certain infections.

In response to this dilemma, on July 9, 2012, President Barrack Obama signed into law the Generating Antibiotic Incentives Now, or GAIN, provisions of the FDA's Safety and Innovation Act. The act gives innovative companies financial incentives for developing new antibiotics by extending their exclusivity period by five years, giving them more time to recoup their investment costs. Drugs that fall under the GAIN provisions also receive fast track and priority review status and undergo an expedited regulatory approval process with the FDA.[1] As a result, three new antibiotics for the treatment of acute bacterial skin and skin structure infections have been approved by the FDA for sale in the United States in the last four months.

In May, Dalvance (dalbavancin), manufactured by Durata Therapeutics, was the first drug designated as a Qualified Infectious Disease Product (QIDP) to receive FDA approval. QIDP designation is applied to antibacterial or antifungal human drugs intended to treat serious or life-threatening infections. Dalvance, a lipoglycopeptide antibiotic, interferes with cell wall synthesis by binding to D-alanyl-D-alanine terminus of the stem pentapeptide in nascent cell wall peptidoglycan, thus preventing cross-linking. It is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria like *Staphylococcus aureus* (including methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains) and *Streptococcus pyogenes*. The treatment is administered as a 2-dose regimen of 1000 mg IV followed 1 week later by 500 mg IV, both infused over 30 minutes.[2]

The second antibiotic to gain FDA approval and QIDP designation was Sivextro (tedizolid), manufactured by Cubist Pharmaceuticals. Approved in June, Sivextro is a protein synthesis inhibitor that interacts with the bacterial ribosome and inhibits bacterial protein translation. It is indicated to treat patients with ABSSSI caused by certain susceptible bacteria, including *Staphylococcus aureus* (including MRSA and MSSA), various *Streptococcus* species, and *Enterococcus faecalis*. Sivextro is available for intravenous and oral use. The recommend dose of Sivextro is 1 tablet (200 mg) by mouth daily for 6 days, or as an intravenous (IV) infusion (200 mg) over 1 hour given daily for 6 days.[3]

Orbactiv (oritavancin), the third antibiotic approved to treat ABSSSI, gained FDA approval on August 6th. Orbactiv, manufactured by The Medicines Company, is a lipoglycopeptide antibacterial drug indicated for the treatment of ABSSSI caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms. Orbactiv is administered intravenously as a 1200 mg single dose infusion over three hours. The Medicines Company says that Orbactiv is the only antibiotic approved for acute bacterial skin and skin structure infections with a once-only administration.[4]

In April, the World Health Organization published its' first global report on antibiotic resistance, denouncing resistance as a major threat to public health. This commitment to develop new antibiotic options by pharmaceutical companies is encouraging, however, it is only the beginning of a lengthy battle against antibiotic resistance.

References:

1. Cox, Edward M. *FDA Voice*. U.S. Food and Drug Administration. www.fda.gov. July 28, 2014. Accessed August 18, 2014.
2. U.S. Food and Drug Administration. *FDA approves Dalvance to treat skin infections*. FDA website. www.fda.gov. May 23, 2014. Accessed August 18, 2014.
3. U.S. Food and Drug Administration. *FDA approves Sivextro to treat skin infections*. FDA website. www.fda.gov. June 20, 2014. Accessed August 18, 2014.
4. U.S. Food and Drug Administration. *FDA approves Orbactiv to treat skin infections*. FDA website. www.fda.gov. August 6, 2014.

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How Access Helps You

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A Qualified Access Patient

- Likely takes 8 or more maintenance medications
- Frequently calls or visits
- Presents adherence concerns
- Could have newly diagnosed or exacerbated diagnoses
- Sees multiple doctors

PHARMACY FACTS!

ORDER CUTOFF GUIDELINES

- Monday – Friday:
  - ◊ 1st Run – Refills 10:30AM; New orders 11:30AM
  - ◊ 2nd Run – Refills 3:00PM; New orders 6:00PM
- Saturday
  - ◊ 1st Run – Refills 11:00AM; New orders 1:00PM

** For any new order or refill sent after the respective cutoff, please call the pharmacy or on-call pharmacist if it is needed before the next scheduled delivery.
** Deliveries leave the pharmacy at the following times: 1st Run 1:00PM (2:00PM on Saturday); 2nd Run 7:00PM

Rescheduled: DEA Reclassifies Tramadol and Hydrocodone Containing Products (HCPs)

On August 18, 2014, tramadol (Ultram®) and all tramadol containing products (e.g. Ultracet®) became a Schedule IV controlled substance in all states under federal law. The DEA rescheduled tramadol due to its abuse potential. Tramadol is now subject to the same prescribing restrictions as other Schedule IV controlled substances. This includes, but is not limited to the following: All tramadol products should now be stored under double lock, an initial inventory of all tramadol products in the facility should have been completed as of August 18, 2014, and each prescription for a tramadol product should be documented on a controlled drug record/log (aka. declining inventory sheet).

Just after the reclassification of tramadol, the DEA voted to reschedule hydrocodone combination products (HCPs) from schedule III to schedule II on August 21, 2014. As of October 6, 2014, all schedule II requirements will become applicable to HCPs. This includes requirements related to DEA registration, security protocols, labeling and packaging, inventory, and recordkeeping and reporting. Since HCPs were already a controlled substance, the biggest changes that will be seen at the facility level include the following: Each prescription for a HCP will need an original prescription to be written for every product dispensed by the pharmacy, and no refills may be authorized for HCPs, but physicians can write up to three prescriptions at once with a "Do Not Fill Until" date on each prescription. Blue Ridge Pharmacy's procedures for HCPs will be the same as they are now for other schedule II medications such as morphine, oxycodone, fentanyl, amphetamine products, etc. The pharmacy will accept faxed prescriptions sent directly from the prescriber; if the prescription is written on a prescription pad and sent with the patient, our drivers will request the original prescription when they drop off the medication.

Please contact the pharmacy if you have any questions regarding these changes.

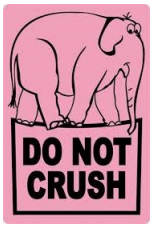
A *CRUSHING* QUESTION

A question the pharmacy receives on a regular basis is whether or not certain medications can be split and/or crushed. There are many reasons that may require a medication to be split or crushed. Often times, residents have trouble swallowing a tablet or capsule and so they try to break, chew, crush, or mix the medication in food or drink. Also, residents that are unable to swallow and have a feeding tube require medications to be administered in a solution which may necessitate crushing. Finally, cost may also play a role due to the commercial availability of certain strengths and/or insurance coverage.

However, not all medications can be crushed or split, and medication errors and adverse drug events can occur if the wrong medication is crushed or split. One reason is that certain medications have a special release mechanism designed to slowly release a certain amount of medication over a given extended time. If the medication is altered or destroyed in any way, the medication can be released too fast and cause a bad effect. Crushing medications with an enteric coating can destroy the mechanism that was designed to protect the gastric mucosa from irritation or to protect the medication from gastric acids.

As **a general rule of thumb**, the following medications should not be split or crushed:

- Extended release/sustained release/delayed release tablets
- Enteric or specially coated tablets
- Sublingual/buccal/ODT tablets
- Asymmetrical or very small tablets
- Teratogenic medications
- Hazardous medications
- Capsules
- Drugs with very precise dosing requirements



Whenever possible, the pharmacy will package the exact dose of the medication with clear instructions on how the medication is to be administered. If the medication requires crushing, we will provide the medication in a liquid or crushable formulation when available and allowed. We also encourage all of our facilities to maintain an up-to-date reference of medications that should not be crushed (see below), and to follow all pharmacy and facility policy and procedures on how to crush medications.

If you have questions regarding a specific medication and information cannot be found on any of the resources below, please call the pharmacy or drug manufacturer for more information.

Resources:

- ISMP's "Oral Dosage Forms That Should Not Be Crushed" List (available at http://www.ismp.org/tools/donotcrush.pdf)
- Davis's Drug Guide "Do Not Crush!" (available at http://www.drugguide.com/ddo/ub/view/Davis-Drug-Guide/109642/all/)
- Pharmacist's Letter "Meds That Should Not Be Crushed" (available at www.pharmacistsletter.com)

References:

1. Splitting tablets challenges you and your residents. Long-Term Care Advise ERR. 2014; 8(2). http://www.ismp.org/newsletters/longtermcare/issues/LTC201408.pdf. Accessed August 2014.
2. Mitchell J. Oral dosage forms that should not be crushed. Institute of Safe Medical Practices online. Available at http://www.ismp.org/tools/donotcrush.pdf. Accessed August 2014.
3. PL Detail-Document, Meds That Should Not Be Crushed. Pharmacist's Letter/Prescriber's Letter. August 2014.
4. Oral Medications That Should Not Be Crushed or Altered. Lexi-Comp Online™, Hudson, Ohio: Lexi-Comp, Inc. Available at http://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/4227. Accessed August 2014.

Get to Know...

Charles Allen, PharmD

Charles grew up in Raeford, NC and graduated from the University of North Carolina at Pembroke with a Bachelor's degree in Business Management. After working a few years in the business field, Charles returned to school and received his pharmacy degree from Campbell University in Buies Creek, NC. He worked as the Pharmacy Director for NCS HealthCare in Benson, NC for several years. He then became the Pharmacy Director for an independent grocery store chain. He implemented a pharmacy program for the grocery store chain and grew it to six pharmacies throughout the chain. In July, 2014, Charles began working with Blue Ridge Pharmacy as the Pharmacy Director for Blue Ridge's newest location in Cary, NC. Charles and his wife, Xan, have two kids, Layla and Jack. Charles likes to spend time away from work with his family and watching sports.

"Never give up! Failure and rejection are only the first steps to succeeding." —Jim Valvano

Cody Honeycutt, CPhT

My name is Cody Honeycutt. I work at Blue Ridge Pharmacy as a fill technician, but I'm soon going to be working as an order entry technician. I'm from Burnsville, North Carolina, and I started as a pharmacy technician at Ingles. I am going to school to become a Medical Lab Tech, but I have not finished my degree yet. My favorite hobbies are hiking and fishing. I love to watch football and spend time outdoors. I recently got married at the beginning of 2014. My wife is from the Philippines, and I've been there 5 times throughout our relationship. It's one of my favorite places in the world, and I would like to retire there.

"A person who has never made a mistake has never tried anything new." – Albert Einstein

Contact Us!

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