Fall is practically upon us and with it those once balmy, final days and nights of summer will soon be but recent memories. The end of one ushers in the revving-up of the other and, with it, a shift in focus and objectives to what we as healthcare providers must do to get everyone ready for fall. Roll-up those sleeves, folks, because it’s vaccine time!

While the Centers for Disease Control and Prevention (CDC) maintain the U.S. immunization schedules, it is important to note that these schedules are reviewed and updated every year. Therefore, to ensure that we provide the most appropriate vaccinations to our patients and avoid/limit outbreaks, it is imperative to review and utilize the most current versions of these schedules. The current vaccination schedule can be found at:

http://www.cdc.gov/vaccines/schedules/hcp/index.html

Now, while there have not been many major changes to the adult schedule since 2011, there have been some changes that healthcare professionals need to be aware of, including:

- HPV Vaccines: There was an update to the footnote for HPV vaccines to include routine vaccination for males ages 11-12 years old with catch-up recommendations for those 13-21 years old. In addition, there is the new recommendation that men ages 22-26 who have not been previously vaccinated and who are immunocompromised, or have HIV, or who have sex with men receive the HPV vaccine as well.

- Zoster Vaccine: The CDC has affirmed their position that while the FDA has approved the zoster vaccine for those ages 50 years old and older, they still recommend only vaccinating adults who are 60 years old and older.

- Hepatitis B Vaccines: The hepatitis B vaccine footnote has been updated to indicate that adults under 60 years of age who have diabetes should receive the vaccine as soon as possible after diagnosis. Also, at the discretion of the clinician, those over the age of 60 with a diagnosis of diabetes may also receive this vaccine. However, this depends on their need for assisted blood glucose monitoring, their likely immune response to the vaccine, and their likelihood of acquiring hepatitis B.

- Meningococcal vaccines: More detailed information has been added concerning the meningococcal vaccines based on specific age and risk groups. For example, updates include two doses of meningococcal conjugate vaccine quadrivalent (MCV4) at least 2 months apart for adults with functional asplenia or persistent complement component deficiencies and, likewise, people infected with HIV who are vaccinated should also receive two doses.
Pertussis Vaccines: Lastly, one very hot topic in vaccination preparedness this year concerns the administration of the Tdap (Tetanus Toxoid, Reduced Diptheria Toxoid, and Acellular Pertussis) vaccine. This topic has garnered a great deal of attention as the cases of pertussis, also known as “whooping cough,” have been rising over the last few years across the nation. In Pennsylvania, for example, the infection rate has reportedly increased two- to three-fold since this time last year. In Washington state, the rise in pertussis cases has been so prominent that in April, an outbreak was declared an epidemic. The increasing rates and the accompanying concern has prompted the CDC’s Advisory Committee on Immunization Practices (ACIP) to issue updated recommendations relating to the administration of the Tdap booster:

1. Since February 2012, it has been recommended that all adults 65 and older should receive a Tdap booster.
2. Additionally, following a thorough review, on June 29, 2012 the ACIP recommend that all adults 19-65 who have not received a dose of Tdap or whose vaccination status is unknown should receive one dose. It is further suggested that the Tdap booster be given regardless of the interval since the patient’s last tetanus or diphtheria-containing vaccine. This dose will replace one of their Td 10-year boosters. After receiving a Tdap, the patient should receive Td boosters as outlined in the MMWR (Morbidity and Mortality Weekly Report) public guidelines.
3. A Tdap booster is specifically suggested for pregnant women more than 20 weeks gestation, adults of any age who are in close contact with infants under 12 months of age and healthcare professionals.
4. While one Tdap formulation under the name Boostrix® has been approved by the FDA as safe for those older than 65 years, the ACIP recommend that if it is unavailable, the Tdap vaccine Adel® could be used in its place. Through their research, they have found that Adel® provided protection and non-inferior safety.

In a press briefing on the topic of rising pertussis cases held in July, it was mentioned that in 2010, only 8% of adults in the United States had any history of receiving a Tdap booster. As children under 7 years of age should only receive their first of five Dtap vaccinations, (which is also comprised of diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens but is distinct from the Tdap adults receive) starting at 6 weeks of age, those younger or who otherwise need to catch-up are left unprotected. This is especially concerning as babies tend to suffer the poorest of outcomes once infected with pertussis. For this reason, ACIP stresses that healthcare providers make sure that the individuals who are around young babies are up-to-date with their pertussis vaccine.

AND, as a reminder . . .

Last— but certainly not least of all—no vaccination discussion would be complete without mention of the influenza vaccine. As was the case last year, the CDC continues to recommend annual influenza vaccination of all persons ages 6 months and older. Covered influenza vaccine formulations include: Afluria® (syringe & vial), Fluarix® (syringe), Flulaval® (vial), Flumist® (nasal spray), Fluvirin® (syringe & vial), Fluzone® (vial), Fluzone High-Dose® (syringe), Fluzone intradermal (syringe) and Fluzone Pedi® (syringe). It is worth mentioning that these formulations (except for the intradermal and high-dose formulations) are also covered at the pharmacy level; so members can be vaccinated in a pharmacy.

And there you have it; a quick synopsis of some of the more noteworthy changes and recommendations to the adult immunization schedule for 2012. So, with that, let’s roll those sleeves up (yours and your patients’) once more for good measure and get to it!

References:

1. CDC: Updates Recommendations for Use of Tetanus Toxoid, Reduced Diptheria Toxoid, and Acellular Pertussis (Tdap) Vaccine in Adults Aged 65 Years and Older – Advisory Committee on Immunization Practices (ACIP), 2012. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6125a4.htm; as accessed 8/3/2012.
New information regarding QT prolongation with ondansetron (Zofran)

The FDA is announcing to health care professionals and the public that preliminary results from a recently completed clinical study suggest that a 32 mg single intravenous dose of ondansetron (Zofran®) may affect the electrical activity of the heart (QT interval prolongation), which could pre-dispose patients to develop an abnormal and potentially fatal heart rhythm known as Torsades de Pointes. GlaxoSmithKline (GSK) has announced changes to the Zofran drug label to remove the 32 mg single intravenous dose. The updated label will state that ondansetron can continue to be used in adults and children with chemotherapy-induced nausea and vomiting at the lower intravenous dose recommended in the drug label, a dose of 0.15 mg/kg administered every 4 hours for three doses; however, no single intravenous dose should exceed 16 mg. Information from the new clinical study will be included in the updated drug label. The FDA will evaluate the final study results when available, and will work with GSK to explore an alternative single dose regimen that is both safe and effective for the prevention of chemotherapy-induced nausea and vomiting in adults.

References:

Formulary

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| Zyprexa® (Olanzapine) tablets | Treatment of schizophrenia  
-Acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder.  
-Adjunct to valproate or lithium in the treatment of manic or mixed episodes associated with bipolar I disorder. | -Schizophrenia in adults: Start at 5-10 mg once daily. In adolescents: Start at 2.5-5 mg once daily.  
-Bipolar I Disorder (manic or mixed episodes) in adults: Start at 10 or 15 mg once daily. In adolescents: Start at 2.5-5 mg once daily.  
-Bipolar I Disorder (manic or mixed episodes) with lithium or valproate in adults: Start at 10 mg once daily. | Tablets (not scored): 2.5, 5, 7.5, 10, 15, 20 mg                                           |
| Daliresp® (roflumilast) tablet | Daliresp® is indicated as a treatment to reduce the risk of Chronic Obstructive Pulmonary Disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. | One 500 mcg tablet per day, with or without food. | Tablets: 500 mcg                              |
| Atorvastatin® (Lipitor) tablets | Reduce the risk of MI, stroke, revascularization procedures, and angina in patients without Congenital Heart Disease, but with multiple risk factors. | Recommended starting dose: 10 or 20 mg once daily. | Tablets: 10 mg, 20 mg and 80 mg (60 mg was previously added to formulary) |
| First-lansoprazole* and First-omeprazole* | Short-term treatment of active duodenal ulcers, Helicobacter pylori eradication, maintenance of healed duodenal ulcers, short-term treatment of active benign gastric ulcer, healing of nonsteroidal anti-inflammatory drug–associated gastric ulcers, risk reduction of FGAD–associated gastric ulcers, gastroesophageal reflux disease, maintenance of healing of erosive esophagitis, pathological hypersecretory conditions (including Zollinger-Ellison syndrome) and heartburn. | Varies depending on indication. | -First-lansoprazole: 3 mg/ml suspension  
-First-omeprazole: 2 mg/ml suspension |

References:
## Product Updates

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<td>Surfaxin® (Lucinactant)</td>
<td>SURFAXIN® Intratracheal Suspension is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN® reduces the incidence of RDS at 24 hours and mortality due to RDS.</td>
<td>Endogenous pulmonary surfactant lowers surface tension at the air-liquid interface of the alveolar surfaces during respiration and stabilizes the alveoli against collapse at resting transpulmonary pressures. A deficiency of pulmonary surfactant in premature infants results in RDS. SURFAXIN® compensates for the deficiency of surfactant and restores surface activity to the lungs of these infants.</td>
<td>The recommended dose of SURFAXIN® is 5.8 mL per kg birth weight. Up to 4 doses of SURFAXIN® can be administered in the first 48 hours of life. Doses should be given no more frequently than every 6 hours.</td>
<td>Intratracheal Suspension: 8.5 mL suspension in a glass vial. Each mL contains 30 mg phospholipids (22.50 mg dipalmitoylphosphatidylcholine (DPPC) and 7.50 mg palmitityloleoyl-phosphatidylglycerol, sodium salt (POPG, Na)), 4.05 mg palmitic acid (PA), and 0.862 mg sinapultide.</td>
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<td>Omontys® (Peginesatide acetate)</td>
<td>OMONTYS® is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis.</td>
<td>OMONTYS® binds to and activates the human erythropoietin receptor and stimulates erythropoiesis in human red cell precursors in vitro.</td>
<td>Initial treatment: 0.04 mg per kg body weight administered once monthly. Conversion from another ESA: dose once monthly based on the total weekly epoetin or darbepoetin alfalfa dose at the time of conversion.</td>
<td>Single use vials: 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 25 mg/0.5 mL, and 6 mg/0.5 mL. Single use pre-filled syringes (preservative-free): 1 mg/0.5 mL, 2 mg/0.5 mL, 3 mg/0.5 mL, 42 mg/0.5 mL, 5 mg/0.5 mL, and 6 mg/0.5 mL. Multiple use vials (with preservative): 10 mg/mL, 20 mg/2 mL.</td>
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<td>Amyvid® (Florbetapir F-18)</td>
<td>AMYVID® is a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer’s Disease (AD) and other causes of cognitive decline. A negative AMYVID® scan indicates sparse to no neuritic plaques, and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient’s cognitive impairment is due to AD. A positive AMYVID® scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. AMYVID® is an adjunct to other diagnostic evaluations.</td>
<td>AMYVID® binds to β-amyloid plaques and the F 18 isotope produces a positron signal that is detected by a PET scanner. In vitro binding studies using postmortem human brain homogenates containing β-amyloid plaques, the dissociation constant (Kd) for f AMYVID® was 3.7 ± 0.3 nM. The binding of AMYVID® to β-amyloid aggregates was demonstrated in postmortem human brain sections using autoradiographic methods, thioflavin S and traditional silver staining correlation studies as well as monoclonal antibody β-amyloid-specific correlation studies. AMYVID® binding to tau protein and a battery of antibodies had no significant correlation with plaques.</td>
<td>Administer 370 MBq (10 mCi) as a single intravenous bolus in a total volume of 10 mL or less. Obtain 10-minute PET images starting approximately 30 to 50 minutes after intravenous injection. Image interpretation: Refer to full prescribing information. The radiation absorbed dose from a 370 MBq (10 mCi) dose of AMYVID® is 7 mSv in an adult.</td>
<td>Multidose vials for injection: 10 mL, 30 mL, and 50 mL vials containing clear, colorless solution at a strength of 300–1900 MBq/mL (13.5–57 mCi/mL). AMYVID® at End of Synthesis (EOS).</td>
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<td>Stendra® (Avanafil)</td>
<td>STENDRA® is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction.</td>
<td>The physiologic mechanism of erection of the penis involves release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation. NO then activates the enzyme guanylatecyclase, which results in increased levels of cGMP, producing smooth muscle relaxation in the corpus cavernosum and allowing inflow of blood. STENDRA® has no direct relaxant effect on isolated human corpus cavernosum, but enhances the effect of NO by inhibiting PDE5s, which is responsible for degradation of cGMP in the corpus cavernosum. Because sexual stimulation is required to initiate the local release of nitric oxide, the inhibition of PDE5s has no effect in the absence of sexual stimulation.</td>
<td>For most patients, the starting dose is 100 mg taken approximately 30 minutes before sexual activity, on an as needed basis. Take STENDRA® no more than once a day. The dose may be increased to 200 mg or decreased to 50 mg based on efficacy and/or tolerability. Use the lowest dose that provides benefit. STENDRA® may be taken with or without food. Do not use STENDRA® with strong CYP3A4 inhibitors. If taking a moderate CYP3A4 inhibitor, the dose should be no more than 50 mg in a 24-hour period. In patients on stable alpha-blocker therapy, the recommended starting dose of STENDRA® is 50 mg.</td>
<td>Tablets: 50 mg, 100 mg, 200 mg</td>
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<tr>
<td>Drug</td>
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<td>Elelyso® (Taliglucerasealfa)</td>
<td>ELELYSO® for injection is a hydrolytic lysosomal glucocerebroside–specific enzyme indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease.</td>
<td>ELELYSO® catalyzes the hydrolysis of glucocerebroside to glucose and ceramide. In clinical trials, ELELYSO® reduced spleen and liver size, and improved anemia and thrombocytopenia.</td>
<td>60 Units/kg administered every other week as a 60–120 minute intravenous infusion. Patients currently being treated with imiglucerase for Gaucher disease can be switched to ELELYSO®. Patients previously treated on a stable dose of imiglucerase are recommended to begin treatment with ELELYSO® at that same dose as when they switch from imiglucerase to ELELYSO®. Physicians can make dosage adjustments based on achievement and maintenance of each patient’s therapeutic goals. Clinical trials have evaluated doses ranging from 11 Units/kg to 73 Units/kg every other week.</td>
<td>For injection: lyophilized powder for reconstitution with diluent. Available in 200 Unit single-use vial.</td>
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<td>Belviq® (Lorcaserin hydrochloride)</td>
<td>BELVIQ® is a serotonin 2C receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes).</td>
<td>BELVIQ® is believed to decrease food consumption and promote satiety by selectively activating 5-HT2C receptors on anorexigenic pro-opiomelanocortin neurons located in the hypothalamus. The exact mechanism of action is not known.</td>
<td>One tablet of 10 mg twice daily. Discontinue if 5% weight loss is not achieved by week 12.</td>
<td>10 mg film-coated tablets.</td>
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<td>Myrbetriq® (Mirabegron)</td>
<td>MYRBETRIQ® is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.</td>
<td>MYRBETRIQ® is an agonist of the human beta-3 adrenergic receptor (AR) as demonstrated by in vitro laboratory experiments using the cloned human beta-3 AR. MYRBETRIQ® relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 AR which increases bladder capacity. Although MYRBETRIQ® showed very low intrinsic activity for cloned human beta-1 AR and beta-2 AR, results in humans indicate that beta-1 AR stimulation occurred at a MYRBETRIQ® dose of 200 mg.</td>
<td>Recommended starting dose is 25 mg once daily, with or without food. 25 mg is effective within 8 weeks. Based on individual efficacy and tolerability, may increase dose to 50 mg once daily. Swallow whole with water, do not chew, divide or crush. Patients with Severe Renal Impairment or Patients with Moderate Hepatic Impairment: Maximum dose is 25 mg once daily. Patients with End Stage Renal Disease (ESRD) or Patients with Severe Hepatic Impairment: Not recommended.</td>
<td>Extended-release tablets: 25 mg and 50 mg.</td>
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</tbody>
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References:

Formulary Website Access
Access the Keystone Mercy Website 24 hours/7 days a week at www.keystonemercy.com/pharmacy/formulary/online/index.aspx
The formulary is updated on a quarterly basis.
We recommend adding this link as a favorite in your computer’s web browser for easy access.