SOP Newsletter

Drug Information News From the School of Pharmacy Faculty Members

July 2013; Vol 1, issue 2

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NEW DRUG OF THE MONTH

Dalal Hammoudi, MSc

FDA approves dabrafenib and trametinib for the treatment of unresectable or metastatic melanoma in selected patients.

Key point: In May 2013, the U.S. Food and Drug Administration approved dabrafenib and trametinib, for patients with metastatic or unresectable melanoma, the most dangerous type of skin cancer. These two new drugs are approved with a companion giagnostic genetic test called the THxID BRAF test that will help determine if a patient's melanoma cells have the V600E or V600K mutation in the BRAF gene.

Finer points: Approximately half of melanomas have a BRAF gene mutation. The product of BRAF gene is a protein kinase involved in cell division, differentiation, and secretion. Dabrafenib and trametinib have slightly different mechanisms of action, but they are both available as tablets for oral administration, and they are approved as single agents, not as a combination treatment.

Dabrafenib is a BRAF inhibitor and is approved for use in patients with melanoma whose tumors express the BRAF V600E gene mutation. It was approved on the basis of data from the BREAK 3 study, conducted in 250 patients with previously untreated BRAF V600 mutation–positive metastatic melanoma. It showed that in such patients, dabrafenib significantly improved the median progression-free survival compared with chemotherapy with dacarbazine (5.1 vs 2.7 months; $P < .0001$).

Trametinib acts as a mitogen-activated, extracellular signal-regulated kinase inhibitor (MEK inhibitor). It is the first drug in this class to be approved and is indicated for use in patients with whose tumors express the BRAF V600E or V600K gene mutations. Trametinib was approved on the basis of the METRIC study, conducted in 322 patients with previously untreated BRAF V600E and/or V600K mutation–positive metastatic melanoma. It showed that in such patients, trametinib significantly improved the median progression-free survival compared with chemotherapy with dacarbazine or paclitaxel (4.8 vs 1.5 months; $P < .0001$).

The most serious adverse effects reported in patients receiving dabrafenib include an increased risk for cutaneous squamous cell carcinoma, while the most serious adverse effects reported in patients receiving trametinib include heart failure, lung inflammation, skin infections, and loss of vision. Both drugs carry the potential to cause fetal harm in women of childbearing age and infertility in men and women. However, the greatest problem with the BRAF inhibitors in the treatment of melanoma has been the lack of long-lasting response, with average duration of 5 to 6 months.

UPDATES IN

What you need to know: BRAF mutations are identified in 40-50% of patients with melanoma. Treatment of these patients with either the BRAF inhibitor dabrafenib or the MEK inhibitor trametinib is associated with improved clinical benefit compared with treatment with chemotherapy in phase III trials. Selection of these agents requires genetic testing, and represents a promising model of personalized medicine in melanoma management.

Source: 1. Hauschild A et al. Dabrafenib in BRAF-mutated metastatic melanoma: a multicentre, open-label, phase 3 randomised controlled trial. Lancet. 2012. 380(9839):358-65.
2. Flaherty KT et al. Improved survival with MEK inhibition in BRAF-mutated melanoma. N Engl J Med. 2012. 367(2):107-14.
3. The US Food and Drug Administration News and Events; News Release, May 29th, 2013.

ASHP NEWS AND UPDATES

Marwan Akel, PharmD.

Dosing in overweight and obese patients

Key point: Drug dosing in overweight and obese patients can be extremely challenging especially that there is little guidance available to assist the clinicians.

Finer points: In overweight and obese population, the use of traditional doses may not elicit therapeutic concentrations that are linked to the desired outcomes. Alternatively using excessive doses may result in the development of adverse drug reactions (ADR). Therefore, before determining if a medication can be considered in overweight and obese patients, the pharmacists must evaluate the pharmacodynamic and the pharmacokinetic (PK) properties of the drug since these later properties are altered in this population. In fact, lean tissue is increased, but it is decreased as percent total weight, in addition blood flow to fat tissues and creatinine clearance (CrCl) are variable. Newest recommendations discuss the use of low-molecular-weight-heparin (LMWH) and antibiotics in this population.

Dosing LMWH is critical in obese patients since this class of medication is eliminated renally faster than in nonobese patients. Mainly present data support the use of enoxaparin, with doses higher than 40 mg/day for post-operative venous thromboembolism (VTE) prophylaxis and doses higher than 0.5 mg/kg twice daily for surgical intensive care unit patients. Dosing should be based on total body weight, although some references suggest that it should be based on the adjusted body weight, capping is not needed, and once daily administration is not advised. The dilemma is still present for patients weighing greater than 150 Kgs, since there isn't enough information to determine if dosing based on actual body weight is safe in this population.

"Dosing should be based on total body weight and capping is not needed"

Dosing antibiotics in this population is also serious. Factors to consider are: PK variables, clinical scenario, ADR, titration strategy and the need of therapeutic drug monitoring. Recommendations for vancomycin, fluoroquinolones and beta-lactams-most data are with cephalosporins- dictate that higher end of the dosing range is necessary but it is also important to consider that the pharmacodynamic goals can be met.

Many institutions are using the body surface area in dosing drugs for overweight and obese patients even though little evidence supports this strategy. As for dose adjustments in renal impairment, the use of the adjusted body weight in the Cockcroft-Gault equation is the most predictive of the measured CrCL in obese subjects.

"The use of the ABW in the CG equation is the most predictive of the measured CrCL in obese subjects"

Dosing in pediatric obese patients is the most critical point. Clinicians categorize this issue a growing, multifactorial dilemma: The American Academy of Pediatrics (AAP) and the Pediatric Pharmacy Advocacy Group (PPAG) mandate not exceeding the recommended adult dose.

What you need to know: High quality evidence with drug dosing in obesity is lacking. Therapeutic drug monitoring is extremely useful in these scenarios.

Source: 1. Ho et al. Cefazolin dosing for surgical prophylaxis in morbidly obese patients. Surgical infection.2012; 13:33-37
2. Scholten et al. A comparison of two different prophylactic dose regimens of low molecular weight heparin in bariatric surgery. Obes Surg. 2002; 12: 19-24
3. Nutescu et al. Low-molecular-weight heparins in renal impairment and obesity: available evidence and clinical practice recommendations across medical and surgical settings. Ann Pharmacother. 2009; 43:1064-1083
4. Ogden et al. Mean body weight, height, and body mass index, United States 1960-2002. Adv Data Health Vital Stat. 2004; 347- 1-17.
5. AAP. Committee on Drugs and Committee on Hospital Care. Pediatrics 2003; 112: 431.

GASTROENTEROLOGIC DISORDERS

Michelle Cherfan, PharmD.

2013 ACG recommendations on the use of PPIs in the treatment of GERD and their potential risks

Key point: Recent studies, suggest that potential risks associated with the use of Proton Pump Inhibitors (PPIs) include, osteoporosis, hip fracture, vitamin and mineral deficiencies, community acquired pneumonia, clostridium difficile infection, and alerts on the concomitant use of PPIs and clopidogrel. The American College of Gastroenterology (ACG) recently published new guidelines that provide clinical recommendations for the management of Gastoesophageal Reflux Disease (GERD) and on the potential risks associated with the use of PPIs.

Finer points: In the treatment of GERD, the ACG guidelines recommend against the routine global elimination of foods and beverages that can aggravate the condition (including chocolate, caffeine, alcohol, acidic and / or spicy foods). The authors explained that no studies have been conducted to date that have shown clinical improvement in GERD symptoms or complications. The therapy of choice for symptom relief and for the healing of erosive esophagitis is the use of a PPI for 8 weeks, with no significant difference in efficacy of symptom relief among the different agents in clinical trials. There are currently seven available PPIs including three that can be obtained over-the-counter (omeprazole, lansoprazole, and omeprazole-sodium bicarbonate) and four that are available only by prescription (rabeprazole, pantoprazole, esomeprazole, and dexlansoprazole). Newer PPIs may offer dosing flexibility relative to meal timing; Omeprazole-sodium bicarbonate is an immediate-release PPI and dexlansoprazole available in a dual release formulation. All other traditional delayed release PPIs should be administered 30 – 60 min before meal for maximal pH control. Dosing should be initiated at once a day; it can be increased to twice daily in patients with partial response and night time symptoms. When clinically indicated, PPIs are safe in pregnant patients.

The guidelines recommend the following on the potential risks associated with PPIs:

1. Switching PPIs can be considered in patients with partial response or in the setting of side-effects.
2. Patients with known osteoporosis can remain on PPI therapy. Concern for hip fractures and osteoporosis should not affect the decision to use PPI long-term except in patients with other risk factors for hip fracture.
3. PPI therapy can be a risk factor for Clostridium difficile infection, and should be used with care in patients at risk.
4. Short-term PPI usage may increase the risk of community-acquired pneumonia. The risk does not appear elevated in long-term users.

"No change is needed to PPI therapy in patients taking clopidogrel"

5. PPI therapy does not need to be altered in concomitant clopidogrel users as there does not appear to be an increased risk for adverse cardiovascular events. This conclusion was based on data from well-controlled randomized trials, which revealed that in patients using concomitant

clopidogrel and PPI therapy, the risk of adverse cardiac outcomes was 0%.

What you need to know: According to the ACG guidelines, an 8-week course of once-daily PPI therapy should be the initial treatment for GERD. New recommendations included that dexlansoprazole and omeprazole-sodium bicarbonate can be given without regard to meals and that no change is needed to PPI therapy in patients taking clopidogrel.

Source: Katz PO et al. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013;108:308–28.

ENDOCRINOLOGIC DISORDERS

Nisreen Mourad, PharmD.

Ospemifene, a novel selective estrogen receptor modulator for treating dyspareunia associated with postmenopausal vulvar and vaginal atrophy

Key point: Menopause is usually accompanied by vasomotor symptoms along with vulvovaginal atrophy often resulting in dyspareunia. The U.S. Food and Drug Administration (FDA) has recently approved ospemifene (Osphena®) a novel selective estrogen receptor modulator to treat postmenopausal women experiencing moderate to severe dyspareunia.

Finer points: The safety and effectiveness of ospemifene for dyspareunia were established in three randomized, double-blind, placebo-controlled clinical studies of 1,889 postmenopausal women with symptoms of vulvar and vaginal atrophy. After 12 weeks of treatment, results from the first two trials showed a statistically significant improvement of dyspareunia in ospemifene-treated women compared with those receiving placebo. While after the 52 weeks long-term safety trial, results supported the drug's long-term safety in treating dyspareunia. Ospemifene was well-tolerated with most treatment-emergent adverse events being mild or moderate in severity. In fact, common side effects associated with its use may include hot flushes, vaginal discharge, muscle spasms, genital discharge and hyperhidrosis.

However, ospemifene is being approved with a boxed warning that the drug, which has estrogen agonistic effects in the endometrium, is associated with an increased risk of endometrial cancer in women with intact uterus who uses unopposed estrogens. Thus adding a progestin to estrogen therapy reduces this risk. Hence women taking ospemifene should seek medical attention for any unusual vaginal bleeding. Also noted in the boxed warning are the incidence rates of thrombotic, hemorrhagic strokes and deep vein thrombosis, although these rates are considered lower than those seen with estrogen-alone therapy. Accordingly ospemifene should be prescribed for the shortest duration consistent with treatment goals and risks for the individual woman. It is available as 60 mg tablet, to be administered once daily with food.

"Ospemifene carries a black box warning of increased risk of endometrial cancer"

What you need to know: The new approval of ospemifene by the FDA offers an additional treatment option for postmenopausal women seeking relief of dyspareunia.

Source: 1. Portman DJ et al. Ospemifene, a novel selective estrogen receptor modulator for treating dyspareunia associated with postmenopausal vulvar and vaginal atrophy. Menopause 2013; 20 (6):623-30
2. Simon JA et al. One-year long-term safety extension study of ospemifene for the treatment of vulvar and vaginal atrophy in postmenopausal women with a uterus. Menopause 2012 Nov 8
3. Bachmann GA et al. Ospemifene effectively treats vulvovaginal atrophy in postmenopausal women: results from a pivotal phase 3 study. Menopause 2010;17(3):480-6
4. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm341128.htm

INFECTIOUS DISEASES

Fadi Hdeab, PharmD.

Infections may play a role in cognitive decline and dementia

Key point: While certain chronic illnesses (e.g. peptic ulcer disease, Burkitt's lymphoma and cervical cancer) have known infectious etiologies, mainstream research has not elucidated a significant role for microbes in cognitive decline. But emerging data suggest an association between some viruses and bacteria and Alzheimer dementia (AD). Katan and colleagues present epidemiologic evidence of an association between infectious burden (IB) and dementia from a large multiethnic cohort.

Finer points: The Northern Manhattan Study (NOMAS) was a multiethnic stroke-free cohort that enrolled 3,298 participants [greater than or equal to] 40 years of age between 1993 and 2001. Of these, 1,625 subjects (65% women, mean age 69 years, 58% Hispanic) had serologic measurements taken for Chlamydia pneumoniae, Helicobacter pylori, cytomegalovirus, and herpes simplex virus type 1 and type 2. Cognitive status was assessed at baseline using the mini-mental state exam (MMSE) and then annually by a telephone interview. A subset also had the number of APOE*4 alleles (known to increase risk for AD) identified. IB was used as the main predictor, which was determined by the relationship of individual serologic test results to the risk of stroke using estimates from Cox proportional hazard models. In a post hoc analysis, the investigators created a viral burden index (VIB) and also tested its association with cognition in the same manner as the overall IB index.

The results of the study were that the IB index was higher in black and Hispanic subjects, those with less than a high school education, no alcohol intake, and without cardiac disease. Furthermore, the IB index was associated with greater odds of having MMSE [less than or equal to] 24 compared to MMSE > 24 (unadjusted odds ratio = 1.58). The effect of the IB index on MMSE did not differ by APOE genotype. The association between IB index and MMSE was prominent among subjects who were physically inactive, women, had Medicaid or no insurance, and had less than a high school education. However, no relation was found between IB and change in cognition over time based on the annual telephone interviews, either unadjusted or adjusted for demographics and risk factors (P = 0.13). Moreover, findings were similar with both the IB and VIB in that the VIB index was associated with MMSE [less than or equal to] 24 (adjusted odds ratio = 1.22; P = 0.04) but not with change over time during follow up interviews (P = 0.24).

"The infectious burden index was associated with greater odds of having the mini-mental state exam less than or equal to 24"

What you need to know: A measure of IB associated with stroke risk and atherosclerosis was independently associated with cognitive performance in this multiethnic cohort. Past infections may contribute to cognitive impairment

Source: Katan M, et al. Infectious burden and cognitive function. Neurology 2013;80:1209-1215

FOCUS ON

CARDIOVASCULAR DISEASES

Samar Younes, PharmD.

Promising treatment to reduce the risk of heart attack in patients on dialysis

Key point: Atherosclerosis is highly prevalent in patients with severe renal failure, and it advances more rapidly in individuals with renal dysfunction than in healthy individuals. In recent years, the relationship between cardiovascular dysfunction and renal insufficiency has been referred to as the "cardiorenal syndrome". Many factors, such as development of uremic toxin, chronic inflammation, anemia, malnutrition, and renin angiotensin aldosterone system, are considered to affect the cardiovascular system and kidney function.

"Uremic toxins, not removed by hemodialysis, increase the risk of heart attack"

Finer points: New research findings show that uremic toxins, which are not removed by hemodialysis, increase the risk of heart attack. It has also been found that an oral adsorbent, called "AST-120", delays the progression of kidney disease by lowering indoxyl sulfate (IS), thus may also prevent future heart attack. To investigate further, scientists used two groups of mice with kidney failure. The first group received AST-120 and the second group did not. When monocytes taken from both sets of mice were subjected to flow cytometry, Mac-1 expression and oxidative stress was reduced in the group with AST-120. For the first time, a study concludes that AST-120 reduces monocyte inflammation in kidney disease, and may reduce cardiovascular diseases including myocardial infarction and stroke in end-stage kidney patients.

What you need to know: The main finding of this study was that AST-120 inhibited monocyte activation by reducing IS in vivo. This provides new insights on how AST-120 attenuates the progression of atherosclerosis in chronic kidney disease. More studies are needed to determine the precise connection between monocytes in the blood, uremic toxins and cardiovascular diseases.

Source: Ito S et al. Reduction of Indoxyl Sulfate by AST-120 Attenuates Monocyte Inflammation Related to Chronic Kidney Disease. J Leukoc Biol June 2013 93:837-845; doi:10.1189/jlb.0112023

NEUROLOGIC DISORDERS

Etwal BouRaad, PharmD.

Risk of Guillain-Barré Syndrome after H1N1 Influenza Vaccination

Key point: Guillain-Barré Syndrome (GBS) is an acute-onset neuropathy characterized by rapidly progressive weakness that can involve the muscles of respiration and become life-threatening. A higher than usual rate of GBS was found in 1976–1977 in the United States; this may have been related to the administration of "swine" influenza A (H1N1) vaccine. Recent consensus panels have failed to demonstrate a link between modern seasonal influenza vaccines and GBS. However, the emergence of a new 2009 influenza A (H1N1) pandemic strain led to mass vaccination campaigns, a recent study (De Wals et al, 2012) aimed to investigate the relationship between this H1N1 vaccine and GBS

Finer points: The authors studied the population of Quebec. In October 2009, a campaign was initiated to vaccinate all residents older than 6 months (7.8 million people). All physicians in Quebec were informed that GBS was an important reportable condition and all neurologists were contacted twice a month for 6 months to report any GBS cases found in the province. A total of 83 cases of GBS per 3.6 million person-years of observation were confirmed (rate of 2.3 per 100,000 person-years). Of these cases, 25 had received vaccination 8 or fewer weeks prior to the development of GBS and were considered the exposed cases with most patients (19/25),

"Influenza vaccines are effective and safe"

vaccinated 4 or fewer weeks before onset.

Of the 83 confirmed cases of GBS, 67% occurred during a 12-week period starting in mid-October near the beginning of the vaccination campaign.

Using Poisson modeling, the age- and sex-adjusted relative risk of GBS development with vaccination was 2.75 [95% confidence interval (CI), 1.63–4.62] for the 4-week post-vaccination period and 1.80 (95% CI, 1.12–2.87) for the 8-week post-vaccination period. The total number of GBS cases attributable to vaccination using the authors' methods was approximately 2 per 1 million doses of the vaccine.

What you need to know: The data suggest the risks of GBS are small and outweighed by the risks of influenza infection. Whether this applies similarly in other areas of Canada or the world or with more typical seasonal influenza vaccines remains unclear. For now, clinicians should assure their patients concerned about vaccine-associated GBS that influenza vaccines are effective and safe.

Source: De Wals P et al. Risk of Guillain-Barré syndrome following H1N1 influenza vaccination in Quebec. JAMA 2012;308:175.

MEDICATION SAFETY

Jihan Safwan, PharmD.

The hidden hazards of acetaminophen

Key point: Acetaminophen is one of the most widely used analgesic-antipyretics in the world. It is available in hundreds of medications that are used to treat pain, allergies, colds, and flu. Regardless of the fact that this drug is considered a generally safe one, yet still it is associated with many hidden hazards that many patients and health care professional fail to recognize.

"Acetaminophen is one of the most widely used analgesic-antipyretics yet it is associated with many hidden hazards"

Finer points: Based on the drug monograph, if acetaminophen is taken at the maximum recommended dose, 4000 mg daily, it is considered safe. In specific patient populations, the recommended maximum dose is even smaller, due to potential liver toxicity. Based on database reports presented by the American Association of Poison Control Centers and reported to the U.S. Food and Drug Administration (FDA) in 2011, it has been realized that the number of mortalities associated with acetaminophen exposures increased by nearly 100 percent between 1995 and 1999. From 1998 to 2003, this medication has been labeled as the leading cause of acute liver failure in the US, whereby almost 9% of those conditions require a liver transplant. Since that time, the FDA has repeatedly alerted consumers and the healthcare community about this avoidable problem. Based on the above facts, multiple challenges have been introduced concerning acetaminophen consumption in the hospital setting. Those challenges include the following:

1. Inclusion in multiple different combination products in variable amounts
2. Multiple indications for this ingredient in combination or single agent medications
3. Time required to calculate the dose administered over a 24 hour period

In order to try to curb this problem, the FDA has adopted multiple actions in order to help in limiting the morbidity/mortality associated with the use of such a safe drug. Those actions include:

- 1966 → Discovered that large doses could produce liver injury
- 1990's → Increasing labeling requirements
- 2004 → Launched new public education campaign
- 2008-2009 → Collaborated with Information Management to build a calculator in electronic Medication Administration Record (eMAR) to add up the total dose of acetaminophen given to the patient in multiple hospitals
- 2009 → Advisory committee set single dose at 650 mg
- 2011 → Manufacturers new requirements to reduce formulations to 325 mg and add boxed warning on prescription products

Based on the above information, those attempts have been very helpful in reducing

the acetaminophen hazards. The eMAR has been successful in

"Acetaminophen has been labeled as the leading cause of acute liver failure in the US"

reducing the e-alerts from 20 alerts/day in 2009 to <5 alerts/day in 2012.

What you need to know: Many hospitals should attempt to tap into potential within the eMAR and collaborate with information management to apply the dosing calculator. Moreover, patients should be taught about medications and how to find acetaminophen content. Approximately 18,000 people are currently waiting for a liver transplant. Pharmacists can help reduce that number!!!

Source: 1. Larson AM et al. Acute Liver Failure Study Group (ALFSG). Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. Hepatology. 2005; 42:1364-72.
2. Matthew C. "Acetaminophen in Combination With N-Acetylcysteine (NAC) Versus Placebo in Treating Fever". Retrieved 17 November 2012.
3. Lai MW et al. 2005 Annual Report of the American Association of Poison Control Centers' national poisoning and exposure database. Clin Toxicol. 2006;44:803-932.

PHARMACY EDUCATION

Fida Drouby, PharmD.

A guide for effective clinical teaching: an ASHP-based approach (Part 2)

Key point: As discussed in the previous issue, the clinical preceptor has an important role in ensuring an optimal learning experience. Therefore, it is essential to understand and adapt the techniques and approaches of the four-step model: instructing, modeling, coaching, and facilitating. All these steps should be tailored to the student's baseline level of knowledge and understanding.

Finer points: The four-step model includes:

I. **Direct instruction:**

It is not the chief role of the preceptor; however, it can provide a strong learning basis by:

1. Assigning readings (guidelines, articles, clinic or hospital algorithms…) that can be discussed with the preceptor to ensure understanding.
2. Giving lectures focusing on clinically relevant facts and research; enhancing understanding of facts rather than repeating information; and incorporating question-answer sessions
3. Applying case-based teaching where the preceptor can discuss an actual case or a simulated case. The discussion should build on an existing foundation, rather than repeating information

II. Modeling:

Is also called "active" or "focused" observation, where the student will learn from the preceptor who will solve a direct patient case or problem (counseling, DDI, non-compliance…). Modeling can take place during case discussion or an actual clinical encounter. The preceptor should follow three major steps to maximize modeling:

1. Focus on a specific problems or action to be taken, and inform the student in advance to permit closer attention.
2. Be skillful enough to complete the behavior step-by-step and fully explain it to the learners.
3. Briefly discuss the action taken while focusing on three or four points to maximize time efficiency and identify the learner progress.

III. Coaching:

It allows the learner to obtain practical experience under the supervision of an expert. For optimal coaching, the preceptor can follow five major steps:

1. Preselect the patients or encounters in a way appropriate to the learner's level of training, focus on specific problems or action to be taken, and inform the student in advance to permit closer attention learners
2. Ask the learner to perform a previously modeled assignment and then provide criticism and direction that help improve the learner's skill and knowledge.
3. Carry out an extensive patient case discussion.
4. Question the learner by using systematic, limited open-ended questions to help the

learner focus on the learning objectives of this task. If the learner cannot find the answer, the preceptor should give more time to think and ask more questions that can lead to the answer.

5. Provide feedback that supports the strengths, recognizes the weaknesses, and provides a tool for the learner to build strategies for future skills advancement. It is often a written report which evaluates not only scientific knowledge and decisions but also social, ethical, and moral consequences of the judgment taken by the student. It is important to remember that "A practice without feedback is simply repetition".

IV. Facilitating:

The preceptor helps the learners to evaluate and criticize their own clinical decisions and those of others. The six steps of self-evaluation are:

1. Establish criteria (goals and objectives to achieve)
2. Collect data (through feedbacks, case discussions, coaching…)
3. Compare data with the criteria
4. Make a judgment (evaluate own progress)
5. Make a decision (to improve, adjust, search…)
6. Take appropriate action (more readings, case practices…)

What you need to know:

Based on the ASHP practice-based teaching, experimental learning is the application of the knowledge to "real-world" patients' cases. It is essential for the clinical preceptor to be familiar with these steps in order to provide the best clinical practice.

Source: 1. Weitzel K et al.Teaching clinical problem solving: A preceptor's guide. Am J Health-Sys Pharm. 2012; 69: 1588-99.
2. Richetti C et al. Strategies and resources for successful preceptor development. Am J Health-Sys Pharm. 2011; 68: 1837-42.
3. Nimmo CM.. Developing training materials and programs: creating educational objectives and assessing their attainment. In: Nimmo CM,2008.

ALTERNATIVE MEDICINE

Sawsan ElHussein, PhD.

Complementary and alternative medicine: Introduction and definitions

Key point: NCCAM (National Center for Complementary and Alternative Medicine) defines CAM as a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine.

Finer points: The most used of CAM by Americans is "Complementary medicine" which refers to the use of CAM together with conventional medicine, such as using acupuncture in addition to usual care to help lessen pain. Others definitions include, "Alternative medicine" that refers to the use of CAM in place of conventional medicine and "Integrative medicine" that combines treatments from conventional medicine and CAM for which there is some high-quality evidence of safety and effectiveness.

CAM practices are often grouped into broad categories, such as: Natural products, mind and body medicine, and manipulative and body-based practices.

Natural Products is the area of CAM that includes the use of a variety of herbal medicines (also known as botanicals), vitamins, minerals, and other "natural products." Many are sold over the counter as dietary supplements.

Mind and Body Medicine focuses on the interactions among the brain, mind, body, and behavior, with the intent to use the mind to affect physical functioning and promote health. This area includes: Meditation techniques, various styles of yoga, acupuncture and others such as deep-breathing exercises, guided imagery, hypnotherapy, progressive relaxation, qi gong, and tai chi.

A manipulative and body-based practice focuses primarily on the structures and systems of the body, including the bones and joints, soft tissues, and circulatory and lymphatic systems. Two commonly used therapies fall within this category: the Spinal

"CAM practices are grouped into categories: Natural products, mind and body medicine, and manipulative and body-based practices"

manipulation and massage therapy.

Some CAM practices involve manipulation of various energy fields to affect health. Such fields may be characterized as veritable (measurable) or putative (yet to be measured). Practices based on veritable forms of energy include those involving electromagnetic fields (e.g., magnet therapy and light therapy). Practices based on putative energy fields (also called biofields) generally reflect the concept that human beings are infused with subtle forms of energy; qi gong, Reiki, and healing touch are examples of such practices.

Finally, whole medical systems, which are complete systems of theory and practice that have evolved over time in different cultures and apart from conventional or Western medicine, may be considered CAM. Examples of ancient whole medical systems include Ayurvedic medicine and traditional Chinese medicine. More modern systems that have developed include homeopathy and naturopathy.

What you need to know:
Some CAM practices may fit into more than one category. The boundaries between CAM and conventional medicine are not absolute, and specific CAM practices may, over time, become widely accepted.

Source: National Center for Complementary and Alternative Medicine: what is complementary and alternative medicine? http://nccam.nih.gov/health/whatiscam#types

WOMEN'S HEALTH

Diana Malaeb, PharmD.

Ulipristal acetate: a new emergency contraceptive pill

Key point: Ulipristal acetate (Ella®) is a selective progesterone receptor modulator with antagonistic and partial agonistic effects (a progesterone agonist/antagonist) at the progesterone receptor. It binds the human progesterone receptor and prevents progesterone from occupying its receptor. It is approved as a new emergency contraceptive (EC) pill, indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure.

Finer points: When taken immediately before ovulation occurs, ulipristal postpones follicular rupture. Therefore the likely primary mechanism of action for emergency contraception is the inhibition or the delay of ovulation; however, alterations to the endometrium that may affect implantation may also contribute to efficacy.

This new contraceptive pill is available only by prescription in the U.S. and Europe. It is available as a 30mg tablet and can be taken at any time during the menstrual cycle. The tablet should be administered orally once as soon as possible within 120 hours (5 days) after unprotected intercourse and taken with or without food. Consideration should be given to repeat the dose if vomiting occurs within 3 hours of intake. Ulipristal acetate is well-tolerated and the most frequently reported adverse events are headache, nausea, dysmenorrhea, and abdominal pain similar to other approved emergency contraceptives. There are some reports about slight increase in menstrual cycle length. Eventhough no drug interaction studies have been conducted but in vitro data indicate that it is predominantly metabolized by CYP3A4. Therefore drugs or herbal products that induce enzymes, including CYP3A4, may decrease the plasma concentrations of ulipristal acetate, and may decrease its effectiveness.
EC with Ella ® is an occasional method. It should in no instance replace a regular contraceptive method and women should be advised to adopt a regular method of contraception.

What you need to know:
The main impact of findings on practice is the time window of use. This drug provides a consistent reduction of pregnancy risk when used up to 120 hrs after intercourse which means 2 additional days for intervention in comparison to the labeling of other previously approved EC pills.

Source: Gainer E. ella® ulipristal acetate. FDA Reproductive Health Drugs Advisory Committee. June 17, 2010.

Perceptions of pharmacy students, faculty members, and administrators on the use of technology in the classroom

Key point: Technology can enhance the teaching and learning experience through ready access to information, increased collaboration, and student engagement. As higher education institutions increase their use of technology and new technologies are developed, there is increasing pressure on faculty members to use these new technologies in the classroom and to appropriately modify the educational methods they use.

Finer points: A study was conducted to gather and evaluate the perceptions of students, faculty members, and administrators regarding the frequency and appropriateness of classroom technology use at 6 colleges and schools of pharmacy. A total of 466 third-year pharmacy students, 124 faculty members, and 12 administrators participated in the survey. All participating colleges and schools of pharmacy used a variety of educational technologies. Course management systems were the most commonly used classroom technology by faculty members (64%) followed by lecture capture (46%), podcasts (44%), online testing (36%), and audience response systems (31%).

With regards to the course management systems, 92% of the students reported that they used a course management system "frequently" (defined as between 75%-100% of their courses). Additionally, 92% of the students either agreed or strongly agreed that faculty members effectively used this technology, and 91% strongly agreed or agreed

"Tech-savvy and male students preferred greater use of technology in the classroom"

that the course management system enhanced their learning experience. But, 85% of students agreed or strongly agreed that a course management system should be used by more faculty members and in more courses.

As to the audience response system, 37% of students indicated that it was "rarely" used in their courses (defined as <25%), and 30% indicated "sometimes" (defined as 25%-50%). Students had mixed opinions about the effectiveness of faculty members' use of this technology. Results for lecture capture were comparable to that of the audience response system

The study also reports that a minority of students (6%) would have liked to see less technology used in the classroom. Students who considered themselves tech-savvy and male students demonstrated a preference for greater use of technology in the classroom ($p<0.01$and $p=0.02$ respectively).

Faculty members perceived more pressure from colleagues (41%) and administrators (40%) than from students (26%) to incorporate additional technology in the classroom. Eighty-six percent reported having changed their teaching methodologies to meet the needs of the current generation of students. Administrators were faced with the challenge of adopting new educational technologies to meet the increased interest from faculty members and students given the limited resources and support.

What you need to know: Pharmacy colleges and schools use a variety of technologies in their teaching methods, which have evolved to meet the needs of the current generation of students. Students are satisfied with the appropriateness of technology, but many exhibit preferences for even greater use of technology in the classroom.

Source: DiVall MV et al. Perceptions of Pharmacy Students, Faculty Members, and Administrators on the Use of Technology in the Classroom. American Journal of Pharmaceutical Education 2013; 77 (4): 75.

Announcements

On behalf of the whole body of the School of Pharmacy at LIU we would like to:

- Congratulate **Dr. Michelle Cherfan** and **Dr. Fida Drouby** for earning the University Diploma "Principles of Medical Research"
- Congratulate **Dr. Fida Drouby** on her marriage
- Congratulate **Dr. Etwal BouRaad** on her marriage
- Congratulate **Dr. Mohamad Rahal** for the birth of his daughter

Events:

- Organized the 8th school of pharmacy pharmacy day in Bekaa campus on Friday the 31st of May, 2013
- Hosted deans and members of the executive committee of scientific society of faculties of pharmacy in the Arab world. It took take place at LIU- Bekaa campus from the 22nd till the 24th of May, 2013.
- Hosted a dinner for the deans and members of the executive committee at Karamna restaurant in downtown Beirut
- Dr. Marwan Akel and Dr. Katia Iskandar attended the 2013 summer ASHP meeting at Minneapolis, Minnesota from June the 1st till the 5th, 2013.
- Participated and attended the first LIU alumni gathering at Safir Heliopolitan hotel - Raouche
- All pharmacy graduates passed the colloquium exam with a 100% success rate. Congratulations and good luck in your future endeavors.