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Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met June 21, 2011. 1 product was added in the *Formulary*, 1 was deleted, and 4 were designated nonformulary and not available. 2 interchanges were approved, while 5 criteria for uses were changed. 3 drugs were designated high-priority nonformulary drugs.

◆ ADDED

Budesonide-Formoterol (Symbicort® by AstraZeneca)

◆ DELETED

Acetaminophen Drops [80 mg/0.8 mL] (Generic)*

**Nonformulary and not available, when no longer available*

◆ NONFORMULARY AND NOT AVAILABLE

Colesevelam (WelChol®)†

†Patients may not use their own supply for safety reasons

Malathion-Isopropyl Alcohol-Terpinol (Ovide®)

Pyrethrum Extract-Piperonyl Butoxide (eg, RID®)

◆ INTERCHANGES

Symbicort® for **Advair HFA®**

Zosyn® for **Timentin®‡**

‡Only applies during the Timentin® shortage

◆ CRITERIA-FOR-USE CHANGES

Abiraterone (Zytiga®)

Acetylcysteine Inhalation (Generic)§

§Inhaled use as a mucolytic prohibited during the shortage

(continued on next page)

MEDICATION SAFETY

If to err is human, is CPOE divine?

Computerized Physician Order Entry (CPOE) has revolutionized prescribing in both the inpatient and outpatient settings. While some practitioners may be hesitant to change prescribing methods, CPOE has consistently shown to be a safe and effective means of order entry. Some advantages of CPOE include eliminating illegible orders, shortening pharmacy turnaround time, ability to link with drug-drug interaction reports, and fewer look-alike, sound-alike medication errors.[1] CPOE has decreased medication errors in both academic and community hospital settings.[2,3] While up-front costs of CPOE are high, 1 institution showed an 80% return on investment in CPOE.[4]

While numerous benefits of CPOE have been shown in literature, errors still occur following implementation of CPOE.

Utilization of CPOE is expected to increase over the next 10 years with government incentives. Shands at the University of Florida recently initiated EPIC, which includes CPOE and will inevitably bring change to the institution. As such, practitioners should be aware of the benefits and potential risks associated with CPOE.

While numerous benefits of CPOE have been shown in literature, errors still occur following implementation of CPOE. This article will address common errors introduced by CPOE and some ways they can be avoided.

One potential source of error for both physician and pharmacist in a CPOE system is a phenomenon known as "alert fatigue." Before a CPOE system is fine-tuned, practitioners may see multiple alerts of varying severities. Some alerts may not be clinically significant, or may even be nonsensical. Conveniently, CPOE systems provide a way around these alerts via an override function. Studies have shown that the override function is highly used in practice. A study from a single VA medical center showed that over 80% of "significant" warnings were overridden.[5] Moreover, the authors found that this did not decline over time.

While overriding alerts does not often result in harm, errors may be avoided by carefully analyzing alerts. Questions to ask when an alert fires are, "Why did I receive this warning?," "Does the computer know something about the patient that I don't?," "Am I missing something?," and "What is the risk of overriding this warning?," among others. Overriding an alert is often reasonable, but alert awareness will improve safety.

Another issue that may arise with CPOE is a systematic error in the program that allows a mistake to occur. This is most evident upon implementation of CPOE, as errors often manifest after system cutover. Common errors identified in literature include inappropriate dosage form for a required route (eg, capsules for IV administration), selection of an inappropriate product, wrong dose, frequency, or formulation, inappropriate selection of default doses, and missed drug allergies.[6]

Since CPOE often has many drugs with default doses, careful examination of doses prior to signing orders may decrease errors. Each practitioner should be especially careful in early stages of CPOE initiation while learning which drugs have default doses.

In addition to default doses, all medications have default start times. Prior

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Formulary update, from page 1

◆ **CRITERIA-FOR-USE CHANGES (cont.)**

Gefitinib (Iressa®)¶

Ipilimumab (Yervoy®)¶

Vandetanib (no brand name)¶

¶Added to the Chemotherapy Policy

◆ **HIGH-PRIORITY NONFORMULARY DRUGS**

Belimumab (Benlysta®)

Benzyl Alcohol 5% (Ulesfia®)**

Spinosad (Natroba®)**

***Obtained for permethrin-failures*

Symbicort® is a metered-dose inhaler (MDI) that contains a corticosteroid (**budesonide**) and a long-acting beta$_2$-adrenoreceptor agonist (**formoterol**). It is used for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Symbicort® was evaluated proactively because of a high volume of nonformulary use. Advair® Diskus® is a powder inhaler with a corticosteroid and a long-acting beta$_2$-adrenoreceptor agonist. This product has been listed in the *Formulary* and is an alternative for the treatment of asthma and COPD. Advair® contains the inhaled corticosteroid fluticasone and the long-acting beta$_2$-adrenoreceptor agonist salmeterol.

Both Symbicort® and Advair® have been proven effective for the treatment of asthma and COPD. In head-to-head trials between Symbicort® and Advair®, neither has shown superior efficacy. In multiple trials, the safety profiles of both products also appear to be very similar.

Even though the safety and efficacy of Symbicort® and Advair® are similar, some differences were considered. Symbicort® is an MDI and Advair® Diskus® [the dosage form listed in the *Formulary*] is a dry powder inhaler. An MDI may be preferred by some patients over the dry powder inhaler, but it may also be difficult for some patients to administer, considering metered-dose inhalers require some dexterity.

The average daily cost for Symbicort® is about a third the cost of Advair® Diskus®.

Symbicort® was added in the *Formulary* to offer a metered-dose inhaler dosage form of a long-acting beta agonist with a corticosteroid. Advair® HFA, which is a metered-dose inhaler, was designated nonformulary and not available and interchanged to Symbicort® according to the following:

ADVAIR® HFA TO SYMBICORT® INTERCHANGE

Ordered	Dispensed
Advair® HFA 45/21 mcg	Symbicort® 80/4.5 mcg
Advair® HFA 115/21 mcg	Symbicort® 160/4.5 mcg
Advair® HFA 230/21 mcg	Symbicort® 160/4.5 mcg

The current strength of **acetaminophen drops** will be discontinued by all manufacturers. Thus, these drops will be deleted from the *Formulary* and designated nonformulary and not available. The current strength of drops will continue to be purchased and used until commercial supplies are exhausted.

In the near future, a single strength of liquid acetaminophen will be marketed. This is a safety measure meant to prevent confusion between different strength liquid products. The 160 mg/5 mL liquid will remain on the market and listed in the *Formulary.* The 160 mg/5 mL liquid is roughly 1/3 as concentrated as the current drops (80 mg/0.8 mL). Until the 160 mg/5 mL liquid is marketed with appropriate measuring devices, we will continue to use the old version of the drops as long as they are available.

Colesevelam is a bile acid sequestrant that binds bile acid in the intestine and prevents its reuptake and, consequently, decreases serum cholesterol levels. Colesevelam was approved by the FDA in May 2000 for use in lipoproteinemia and hypercholesterolemia. Colesevelam was approved for use in type 2 diabetes mellitus patients in January 2008 based on evidence that shows that it also lowers hemoglobin A1C (Hb A1C). Colesevelam may be beneficial for use in patients with elevated LDL cholesterol and elevated Hb A1C.

In glucose-lowering trials, colesevelam was shown to lower Hb A1C and fasting plasma glucose levels, suggesting the utility of these agents as a potential therapy for type 2 diabetes. There is little credible evidence to support the claimed benefits of less constipation and less drug interactions with colesevelam compared with cholestyramine. Similar to other bile acid sequestrants, colesevelam increases triglyceride levels.

The daily dose of colesevelam requires a patient to take six 625-mg tablets daily to achieve a total dose of 3.75 grams of colesevelam. The tablets are very large and must be taken with meals and a full glass of water. If not taken correctly, colesevelam can cause dysphagia and esophageal obstruction. These disadvantages outweigh the possible advantages of this drug in the inpatient setting. Since cholestyramine is already in the *Formulary,* the opportunity for a patient to remain on bile acid sequestrant therapy exists.

Colesevelam was designated nonformulary and not available and patients cannot take their own supply from home. Alternative therapy to lower blood glucose is available for use in the hospital and the risk of inappropriate administration of the drug outweighs its short-term benefit.

Malathion and **pyrethrum** are pediculicides that were designated nonformulary and not available after a category review of the pediculicides listed in the *Formulary.* A review of pediculicides was done after the recent approval of new agents for the treatment of head lice. Permethrin remains the only pediculicide listed in the *Formulary.*

Head lice (*Pediculus capitis*) are a problem affecting adults and pediatric patients of all socioeconomic backgrounds. Although morbidity from head lice infestations is low, anxiety and stress plague patients and their caregivers. Treatments focus on pediculicidal (adult) and ovicidal (egg) activity, targeting multiple stages of the louse life cycle to maximize efficacy. Due to the incomplete activity of current agents against both live lice and eggs, multiple treatments are often required to eradicate infestations completely. Efficacy of the topical agents has been reported around 80%; however, resistance to commonly used first-line agents represents an increasing problem and has resulted in the need for alternative therapies.

Permethrin 1% is recommended by the American Academy of Pediatrics as a first-line agent due to its proven safety and efficacy profile. Repeat treatments are necessary for complete eradication and should be separated by 7 days, making therapy primarily an outpatient treatment. Due to current safety concerns with agents, second-line therapies should be employed only after failing 2 treatments, as shown by the presence of live lice found 7 days after the second treatment.

Due to the limited morbidity caused by head lice, the minimal risk

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Formulary update, *from page 2*

of spread between patients, and the current efficacy and availability of cost effective agents, **spinosad** and **benzyl alcohol** were designated high-priority nonformulary drugs, which will be ordered for nonemergent use in patients who have failed permethrin.

Spinosad topical suspension is the newest agent for use against *Pediculus capitis*. Its mechanism of neuronal excitation provides both pediculicidal and ovicidal activity, reducing the need for nit combing and repeat treatments. Application of the product is similar to application of other topical agents requiring scalp and hair saturation with the product and a waiting period followed by rinsing of the scalp and hair. Clinical efficacy trials have compared spinosad to permethrin 1% topical application, concluding a higher cure rate and decreased need for multiple treatments found with spinosad therapy. The safety profile is similar to other topical treatments with the most common adverse effects including eye and scalp irritation.

Benzyl alcohol inhibits closure of lice respiratory spiracles resulting in asphyxiation. It is pediculicidal but not ovicidal. It is applied to dry hair to saturate the scalp and hair and left in for 10 minutes, then rinsed. Benzyl alcohol is not used in infants less than 6 month old due to increased risk of systemic absorption.

Timentin® is an extended spectrum penicillin (ticarcillin) combined with a beta-lactamase inhibitor (clavulanic acid) used to treat nosocomial infections. **Zosyn®** has a similar spectrum of activity, including Enterobacteriaceae, Pseudomonas, and anaerobes.

The manufacturer of Timentin® is unable to supply product at this time resulting in a nationwide shortage. A conversion from Timentin® to Zosyn® (piperacillin-tazobactam) is necessary during this shortage. In EPIC, new orders for Timentin® are being guided to Zosyn® and healthcare providers are provided dosage regimens modified for renal function and to optimize Pseudomonas coverage, when needed (similar to the other P&T-approved interchanges).

Abiraterone is a CYP17 inhibitor with a labeled indication for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel. CYP17 is an enzyme required for androgen biosynthesis; thus, abiraterone is similar to other androgen deprivation therapies.

Common adverse effects associated with the use of abiraterone include joint swelling or discomfort, edema, muscle discomfort, hot flushes, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia, and upper respiratory tract infection. Abiraterone is contraindicated in women who are or may become pregnant. Women who are or may be pregnant should not handle abiraterone without gloves.

Abiraterone was not added in the *Formulary*, but it was added in the *Hazardous Drug Storage, Handling, and Administration Policy* in case there is nonformulary use.

Acetylcysteine was originally marketed as an inhaled mucolytic. Now, acetylcysteine is used for 3 primary uses: acetaminophen overdose (primarily IV), for the prevention of radiocontrast-induced nephropathy (RCIN) (primarily orally), and inhaled as a mucolytic. The use for acetaminophen toxicity is most critical; there currently is no problem obtaining IV acetylcysteine.

There is, however, a nationwide shortage of acetylcysteine, which is the result of 1 of 3 manufacturers suspending distribution of product. The other 2 manufacturers have backordered the product, presumably because they cannot meet demand.

Thus, inhaled acetylcysteine was rationed, choosing between inhaled acetylcysteine as a mucolytic or oral use of the inhaled product orally for the prevention of RCIN. The data are limited in the support of inhaled acetylcysteine as a mucolytic. There are also other alternatives (eg, inhaled hypertonic saline). Therefore, the P&T Committee prohibited the inhaled use of acetylcysteine during the shortage. This restriction will be lifted as soon as sufficient supplies of acetylcysteine can be obtained.

Gefitinib, **ipilimumab**, and **vandetanib** are not listed in the *Formular* but were added in the Chemotherapy Policy, requiring that they be ordered on a *Chemotherapy Order Form.* Although inpatient use should be low, these drugs used to treat cancer were added in the Chemotherapy Policy in case there is limited nonformulary use.

Gefitinib and vandetanib are oral kinase inhibitors. Gefitinib has a labeled indication for the treatment of non-small-cell lung cancer. Vandetanib has a labeled indication for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Ipilimumab is a monoclonal antibody that binds to the cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4), which blocks the interaction of CTLA-4 and CD80/CD86 and augments T cell activation and proliferation. It has a labeled indication for the treatment of unresectable or metastatic melanoma. The anti-tumor activity is attributed to an immune response. Ipilimumab is given IV every 3 weeks for 4 doses.

EPIC

P&T committee-approved authorized changes to med lists

The transition from a paper-based to an electronic ordering system (EPIC) has revealed some prescribing issues. To ensure patient safety, these issues require that prescribers change the way they order and discontinue medications. The P&T Committee approved several changes that allow pharmacists to modify orders per the "P&T-Authorized Change" policy. The expectation is that these modifications will be necessary for only a short while as prescribers become more familiar with the system.

- *The P&T Committee approved changes from solid-to-liquid and liquid-to-solid dosage forms.* There are times when patients cannot take their regular tablet or capsule. By switching the patient to a liquid, the medication can be administered. Nursing staff is usually the best judge of what dosage form can be administered. However, requiring the pharmacy or nursing staff to call or wait for a co-signature each time a change is needed could result in an adverse effect on a patient's treatment. Therefore, the approval to switch has been authorized.
- *The committee authorized pharmacists to discontinue a duplicate drug.* Sometimes medical staff order a medication that the patient is already receiving. A pharmacist now can discontinue the first order and use the most recent order, as long as the drugs are the same, the route is the same, and the intent is clear. To prevent duplications, please remember to review the patient's entire medication list and discontinue any duplicate drugs prior to making a change…or just avoid re-ordering drugs the patient is already receiving.

(continued on next page)

Hey! Stop buggin' me!

It is the middle of summer and a good time to review a topic that affects us all — insect repellants. Insect repellants help avoid skin problems (eg, irritation and secondary infections) and can prevent disease transmitted by biting insects (eg, West Nile virus and Lyme disease). In addition, insects can ruin outdoor activities.

Insect repellants should have an inoffensive odor, have an esthetic feel and appearance, protect against insect bites for several hours, and be effective against a broad spectrum of insects. Repellants work by creating a vapor barrier on the skin that is an offensive odor and bad taste for the insect. They are not insecticides and do not kill insects. There are many formulations and multiple ingredients that make selecting a good product difficult. Repellants are useful in preventing bites from mosquitoes, fleas, and ticks.

The Environmental Protection Agency's approved repellents include DEET, picaridin, oil of citronella, oil of lemon eucalyptus, and IR3535. DEET is the most effective and broadly used repellent. DEET has a good safety profile, when used appropriately.

DEET-containing products range in concentration from 5% to 100%, but most products contain less than 40%. For most situations, products containing 10% to 35% DEET will provide adequate protection. Older children can use products with DEET concentrations below 30%, but children less than 2 months old should not use DEET-containing products.

Although most people may not be familiar with picaridin, this ingredient is nearly as effective as DEET and may be preferred by some people. It is odorless and does not feel as sticky or greasy upon application. It is also less likely to irritate skin and is less likely to damage plastics or fabrics like DEET can. Picaridin-containing products are not recommended in children less than 2 years of age.

Oil of citronella, oil of lemon eucalyptus, and IR3535 are less effective agents. Oil of citronella and oil of lemon eucalyptus are plant-based products. IR3535 is a synthetic product that appears to be the least effective. The table on the next page summarizes the general characteristics of these insect repellants. However, DEET and picaridin are more effective and last longer. These agents are recommended when traveling to areas that require insect repellants.

(continued on next page)

	DEET	PICARIDIN	OIL OF CITRONELLA	OIL OF LEMON EUCALYPTUS	IR3535
EXAMPLES	Cutter Backwoods Insect Repellant (23%) Repel Insect Repellant Mosquito Wipes (30%) Off! Deep Woods for Sportsmen Insect Repellant (95%)	Sawyer Premium Insect Repellant (20%) Skin So Soft Bug Guard Plus Picaridin	California Baby Bug Repellant Spray with Citronella	Repel Plant-based Lemon Eucalyptus Insect Repellant	Skin So Soft Bug Guard Plus IR3535 Expedition

Epic, *from page 3*

- *Pharmacists now can discontinue phase-of-care medications when the patient is no longer in that phase of care.* This authorization applies to orders that were signed and held prior to a procedure but incorrectly released after the procedure and the orders already completed. Remember to discontinue medications used for procedures.
- *The P&T Committee allows pharmacists to re-order the medication to match instructions included in the administration instructions or comments.* Sometimes prescribers cannot determine how to order a medication so they include "instructions" or "comments" that should be included in the order. Similarly, when a dosage range order is intended, but only the starting dose is ordered with the titration parameters in the instructions or comments, the pharmacists can correct these orders. Range orders should be specified in the dose field.
- *A pharmacist can now discontinue a drug that has been weaned.* When a drug is stopped by a tapering protocol, sometimes the prescriber fails to discontinue the medication even though it has not been infusing for 24 hours. While it is best that the prescriber discontinues these orders, a pharmacist now can do so.
- *P&T order mode can be used to discontinue ICU-electrolyte orders when a patient is transferred to a floor; Bone Marrow standard electrolyte orders when a patient is transferred to the MICU; and previous electrolyte orders when a patient is started on the CVVH electrolyte protocol.* Prescribers should assess how medication needs change based on the patient's new location or treatment type.
- *Elements of the subcutaneous insulin orders will be stopped when an insulin infusion is started.* Complex order sets, like the subcutaneous insulin orders, include elements that are no longer relevant when a patient starts an insulin infusion.
- *Finally, intravenous drug orders will be modified to be consistent with standard concentrations.* When ordering intravenous infusions (drips) in EPIC, the prescriber has to specify the drug, base solution, concentration, rate, etc. In the paper system, these orders where not as complete. The P&T Committee has previously approved standard concentrations for intravenous medications, so pharmacists will change these fluids to match the standards for adult patients.

GENERAL CHARACTERISTICS OF INSECT REPELLANTS[1]

	DEET	PICARIDIN	OIL OF CITRONELLA	OIL OF LEMON EUCALYPTUS	IR3535
ODOR	unpleasant	*odorless	slightly sweet, lemony smell	pleasant smell	pleasantly scented
DURATION OF PROTECTION	up to 8 to 12 hours *lasts the longest	can last up to 10 hours	shorter duration than the others	last between 4 and 12 hours	variable duration reported in different studies
SPECTRUM OF INSECTS COVERED	mosquitoes, ticks, biting flies, chiggers, fleas *most broad-spectrum	biting flies, mosquitoes, chiggers, ticks, fleas	lacks broad-spectrum activity	mosquitoes, biting flies, gnats	mosquitoes, deer ticks, body lice, biting flies
SAFETY CONCERNS (ALL CONSIDERED LOW LEVEL TOXICITIES)	acute oral, acute dermal, and primary eye irritation	acute oral, acute dermal, and primary eye irritation; acute inhalation toxicity and primary dermal irritation	skin irritation	eye irritation	eye irritation
SUSTAINABILITY	protection shortened by rain, swimming, washing, and sweating				
FEEL AND APPEARANCE	oily, sticky sensation	does not feel sticky/greasy on application	a volatile, liquid oil	oil	light oil
OTHER ADVANTAGES	wide variety of available products	• does not melt plastic • does not stain clothes *Best cosmetic properties	n/a	n/a	n/a
OTHER DISADVANTAGES	• melts plastic • can damage clothing • may reduce efficacy of sunscreens • limited to once-daily use in children	• protection against ticks • may not last as long as a DEET-based products	• probably not effective against ticks • frequent application is needed due to limited effectiveness	irritation when exposed to eyes (avoid application to face)	limited effectiveness compared to DEET and picaridin (more head-to-head studies needed)

Therapeutics, *from page 4*

There are multiple well-done studies comparing the effectiveness of the various insect repellants on the market. However, many of the studies are small and are limited to specific species of mosquitoes. Studies usually measure time to first insect bite. There is known variability in how "attractive" some people are to insects. Gender, age, anhidrotic state, level of activity, CO_2 release, and lactic acid release are all considered variables that affect repellant efficacy. Insect concentration, species of insect, humidity, temperature, wind, and time of day affect whether insects bite. As summarized in the table, DEET and picaridin can be effective as long as 8 to 12 hours. However, protection is shorted by rain, swimming, washing, and sweating.

Skin irritation is the most common adverse effect associated with DEET, especially products with a concentration above 50%. There have been reports of central nervous system effects (eg, slurred speech, confusion) with DEET use, but usually with improper use. Following labeling decreases the chances of adverse effects. There is not much reported about the adverse effects of picaridin, but there is not as much experience with these products.

DEET and picaridin products are most effective and, although not inexpensive, usually provide the best buy for their effectiveness. Some people will prefer the use of plant-based "natural" products, like oil of eucalyptus or citronella. If these products are used, they need to be re-applied frequently to be effective.

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EDITOR, DRUGS & THERAPY BULLETIN
Randy C. Hatton, PharmD

DIRECTOR, PHARMACY SERVICES
Alan Knudsen, MS, RPh

CHAIRMAN, PHARMACY & THERAPEUTICS COMMITTEE
I. David Weiner, MD
Professor of Medicine and Physiology and Functional Genomics
University of Florida, College of Medicine

EDITING, DESIGN, & PRODUCTION
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Medication safety, *from page 1*
to entering orders in a CPOE system, providers were accustomed to indicating the drug, dose, route, and frequency; however, providers must now also examine default start times of medications. This becomes important particularly when doses of regularly scheduled medications are being changed. Most new medication orders are set with a default start time of within the next hour. If a dose is being changed, it is possible that the patient just received a dose of the medication. If the provider does not change the start time of the order with the new dose, the patient could receive more doses than intended in a short period of time.

Few studies have evaluated the temporal effect of error rates following CPOE implementation. One study conducted in the ambulatory setting found that while total medication errors declined 12 weeks after starting CPOE, non-abbreviation medication errors actually increased.[7] The error rate returned to baseline at 1 year. This study emphasizes the importance of taking extra care in initial stages of CPOE use. It may take time to see the safety benefits of CPOE.

CPOE may also introduce errors regarding continuation of home medications. CPOE often lists home medications for each patient. While this feature helps continue or adjust patients' home medications while the patient is hospitalized, lists may be incomplete. Relying solely on electronic data could lead to errors of omission.

◆

As we embark on a new age of technology-driven healthcare, let us strive to improve patient safety and embrace the advances technology has brought to healthcare.

One systematic review found that despite CPOE, 10-61% of patients had an omission of at least 1 home medication.[8] While these omissions often cause no harm, a small number of patients may be significantly affected. Thorough history cannot be replaced by a CPOE system, and due diligence for obtaining medication history should be used after switching systems.

Ultimately, while CPOE is an exceptional tool for patient safety, nothing can replace clinical judgment. CPOE may help steer a practitioner in the right direction, but decision-making is still provider-driven. Awareness of limitations of CPOE and diligence in preventing errors will maximize the effects of CPOE while minimizing harm. As we embark on a new age of technology-driven healthcare, let us strive to improve patient safety and embrace the advances technology has brought to healthcare.

By Brian McCullough, PharmD

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