The Case for Methadone
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Matt Buderer, RPh

PCCA’s 2013 M. George Webber, PhD Compounding Pharmacist of the Year

A third-generation pharmacist and an innovator in his field, Matt Buderer, of Buderer Drug Company in Sandusky and Perrysburg, Ohio, is known for pioneering new compounding techniques, and constantly adding onto his large formulary. Over the years, he has built great relationships with the prescribers and patients in his community. He also has developed strong relationships with his local professional baseball, basketball, and football teams, often working directly with the trainers to help heal players when needed. Matt is committed to finding the right medication or formula the patient can take, tolerate and afford. He runs a drug repository program that allows long-term care pharmacies to donate paid for medications to his pharmacy for indigent patients. He upholds a strong commitment to quality and safety in his pharmacies, and maintains vital relationships with his local legislators on behalf of the pharmacy compounding profession.

PCCA is pleased to bestow this honor upon Matt, and to have him as a member.

Serving compounding pharmacists since 1981, PCCA helps pharmacists and prescribers create personalized medicine that makes a difference in patients’ lives. We are the complete resource for the independent compounding pharmacist, providing the highest-quality products, education and support.

Interested in becoming a PCCA member pharmacy? Check out what our members are saying about membership at www.pccarx.com/testimonials.
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Methadone is most widely known for its use in detoxification and in maintenance treatment of opioid addiction. Increasingly, it has been used for the management of moderate to severe chronic pain.
Adherence: A ‘Building Block’ to Success for Pharmacies and Patients

NCPA released the first national report card on patient adherence last June. Our country got a C plus, but 30 percent of patients got a D or an F. You can survive a C plus on an algebra test, but a failing grade in taking your medication can be fatal. One other important finding was that the more connected patients are with their pharmacist, the more likely they were to take their medications correctly.

NCPA’s new Digital Pharmacist Solution, powered by RxWiki, is an excellent new way for your pharmacy to stay connected to your patients. Many of your patients, and not just the younger ones, are active in social media.

To help combat those increases and diversify revenue, NCPA has identified adherence as a fundamental building block. Deciding that you will implement programs to improve adherence does the following three things:

• It improves your revenue. Even with shrinking margins, more prescriptions equal more revenue. Adherence is so fundamental, NCPA offers Simplify My Meds™, a free program to members that helps patients synchronize their prescriptions. More than 1,100 pharmacies have signed up and more than 31,000 patients have been enrolled. Participating pharmacies are seeing more prescriptions and greater efficiencies in their operation that allow them to expand other patient care services.

• Adherence can improve star ratings. More often now pharmacies are being given report cards on quality measures rather than on number of prescriptions dispensed. Star ratings are becoming relevant to pharmacies. Pharmacies that can improve star ratings are more desirable. So, which would you rather be, a 3-star pharmacy or a 5-star pharmacy?

• It’s the right thing to do for patients. That’s why we became community pharmacists, isn’t it? Drugs don’t work in patients that don’t take them, and that hurts patients and pharmacies alike and results in higher health care costs for all.

B. Douglas Hoey, Pharmacist, MBA
NCPA Chief Executive Officer

DIVERSIFYING YOUR SOURCES of revenue has always been a smart business strategy. It’s more important than ever now to balance the sometimes volatile prescription drug reimbursements, particularly with the lagging MAC payments. Six states now have laws requiring MAC price updates to be done in a timely manner. More states need to enact these bills as we work on solutions to the outbreak of sudden and sharp generic price increases.

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B. Douglas Hoey, Pharmacist, MBA
NCPA Chief Executive Officer
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California Pharmacists Gain Provider Status—Who’s Next?

NCPA congratulates California pharmacists and the California Pharmacists Association (CPhA) on the successful enactment of legislation to expand the services that pharmacists are authorized to provide in the state. This legislation takes important steps to allow pharmacists to provide care at a level they are educated and fully capable of providing. Specifically, it will allow pharmacists to perform physical assessments; order and interpret laboratory tests; refer patients to other providers; start, adjust, and terminate medications under physician protocol; and work with other health care providers to evaluate and manage a patient’s health issues.

The law is also notable for its collaborative approach to other health care providers. It is supported by many health care-related organizations including the California Association for Nurse Practitioners, the California Association of Physician Groups, and the California Hospital Association.

NCPA endorsed the proposal throughout its advancement through the legislative process, including in an Aug. 20 letter of support. The letter cited the growing primary care shortage that is expected to worsen as more Americans gain insurance through the Affordable Care Act. In addition,

Turn Cardboard Displays Into Compelling End-Caps

by Gabe Trahan

There is always the temptation to put cardboard floor displays where they fit and not where they belong. In a few cases, floor displays can end up blocking aisles and become more of an obstacle than the secondary selling venue that the display was intended to be. If you can’t find the perfect home for the display then use what you can! The photo above shows an example of two floor displays that were easily carved up and made into eye-catching signage for an end-cap. The Dimetapp display actually stands on its own, and the Allegra graphic has a large box of Kleenex behind it to serve as a solid base for the sign. This is also great method for recycling floor displays that have either sold down or beginning to show signs of wear. Give it a try and send me a photo of your inspiration (email: gabe.trahan@ncpanet.org).

Things you should know about floor displays:

- Check for price stickers. Many displays do not come with retail stickers.
- Confirm the retails with the product already stocked on the shelf. There should be no discrepancies.
- In many instances a new item that appears in a display will reflect the manufacturer retail and not the store recommended retail! You will need to correct this or you will run the risk of being overpriced.
- Refill or recycle the display as soon as it is sold down by one-third.
- Remove or recycle a display as soon as it begins to look worn.

Gabe Trahan is NCPA’s senior director of store operations and marketing. Gabe uses 30 years of front-end merchandising experience to help NCPA members increase store traffic and improve profits. Visit (www.ncpanet.org) and click on Front-End Overhaul. Watch the videos, read the tips, and view two galleries of photo examples by Gabe. Follow him on Twitter @NCPAGabe for additional tips.
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Nexafed delivers the efficacy your patients expect and the meth-deterring technology you want to help keep your community safe.

References:

Sudafed is a registered trademark of Johnson & Johnson.  
Zephrex-D® is a registered trademark of Westport Pharmaceuticals, LLC.

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Email your recent example of a problem you or a patient has had with a PBM to mike.conlan@ncpanet.org, or fax it to 703-683-3619. We may edit it for length and clarity.

THE AUDIT ADVISOR

HUMANA NOTICE OF INCORRECT CLAIM INFORMATION AUDITS

Q: I just got an audit notice from Humana on “Incorrect Claim Information.” What does it mean and what should I do?

A: Humana recently sent out incorrect claim information audits indicating that claims were submitted with invalid prescriber identifiers. Pharmacies are to submit the correct prescriber identifier to avoid full chargeback while being assessed a $5 administrative fee to correct the claim. In some cases the prescriber is deceased and different steps need to be taken.

PAAS contacted Humana for clarification regarding deceased providers and was told if the correct NPI (National Provider Identifier) number is on the claim, the pharmacy should:
1. Submit a copy of the original prescription.
2. Provide a statement on pharmacy or physician letterhead that the prescriber is deceased and include the month and year they passed away.

PAAS was told it is OK if the prescriber passed away prior to the prescription being dispensed. However, PAAS recommends that pharmacies follow their state laws regarding deceased providers. PAAS was also told by Humana that if the pharmacy used the correct prescriber identifier and the prescriber passed away, the pharmacy would not incur any $5/prescription charges as long as they provided the two items listed above.

PAAS advises pharmacies to submit all documentation via certified mail with return receipt. For additional questions, please contact Humana at 502-476-9400 or email pharmacyauditcompliance@humana.com.

By Mark Jacobs, RPh, PAAS National, the Pharmacy Audit Assistance Service. For more information call 888-870-7227 toll free, or visit (www.paasnational.com).

INDEPENDENT PHARMACY TODAY

Compounding
• The percentage of independent pharmacies providing compounding services has remained almost constant at more than 60% over the past three years.
• The number of compounded prescriptions increased in 2012.
• Compounding is the third-most offered service, preceded by delivery and patient charge accounts.

Source: 2013 NCPA Digest, sponsored by Cardinal Health

Trending—Pharmacists Get Into Tweeting About Their Patient-Centric Deeds

More than 7,100 tweets by pharmacists were sent out in the first-ever #Pharmacist tweet-a-thon. The stories tweeted were diverse and inspiring. Those efforts helped #Pharmacist become the number one trending health care hashtag on Oct. 3. Members from 53 international, national, and state pharmacy associations participated in the tweet-a-thon as well as members from 23 other pharmacy organizations.

Continued from page 6 ➔
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Targeting Adherence: Use a Multi-Faceted Approach
by Tyler Staten, MBA

Compounding can provide a vital link to improved adherence. Adherence has been described by the World Health Organization as a "worldwide problem of striking magnitude" and the average rate of medication adherence in patients with chronic conditions in the United States and other developed countries is an alarming 50 percent. Along with negative health outcomes, another consequence is increasing health care costs, which has been estimated by the New England Healthcare Institute to be approximately $290 billion annually in the United States. Pharmacists have the position to serve patients to improve access to medications, motivation, skills, and knowledge.

How many times have you seen the bins of filled medications overrun with prescriptions that have not been picked up? This is a great opportunity for the pharmacy to interact with patients. Have the cashiers or technicians call and engage the patients why the medications have not been picked up. This could improve medication use, adherence, and motivation. If further questions arise, the patients can be referred to the pharmacist. This also helps to get the filled medications out of the pharmacy and the revenue stream back into your business.

Some patients may have significant barriers to medications that have not been addressed. How do patients feel about their disease state or about the medication they have been prescribed? Do they have a belief system that makes them feel a certain way about taking a medication or type of medication? Do the patients comprehend the instructions or understand what the medication is for? These issues can be addressed and changes can be implemented to put patients more in charge of their medication regimen. Ask open-ended questions about their medications on every visit regarding how and when they take their medications, or if they have had any side effects that have hindered them from taking their medications as a result. Patients should be as familiar with the medications they take as they are with the medical condition it is intended to treat.

From a compounding perspective, a recent survey of compounding pharmacists in independent practice found that pharmacists started conducting more thorough counseling on their compounds, made follow up calls at initiation of therapy, and then decreased the frequency of the phone calls as the patient’s therapeutic goals were being achieved. If patients were not taking their medications, they considered possible dosage regimen modifications that could lead to fewer adverse effects and better adherence. The pharmacists evaluated outcomes to conclude that if patients got their refills in a timely manner, they were satisfied with the results from the medications. These surveyed pharmacists were able to adjust their time in response to patient counseling through effectively using technicians in data entry, dispensing, and clerical functions to allow for the pharmacist’s flexibility. A pharmacy management strategy that would allow for pharmacist flexibility in this area might improve counseling procedures and medication adherence.

With the ongoing and increasing issues of non-adherence and health care spending, it is wise for us as pharmacists to do our part to improve the health outcomes of our patients. 

Tyler Staten, MBA, is a 2014 PharmD candidate at the Harding University College of Pharmacy.
The Office of Civil Rights has been authorized to conduct on-site compliance audits, which are to begin in the first quarter of 2014.

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William Popomaronis, R.Ph., VP-NCPA

For more information, or to sign up with HIPAA Track visit the NCPA bookstore at: www.ncpanet.org/index.php/ncpa-store
Say What? Spell Out Drug Names and Sound Out Doses

A physician recorded a prescription on the pharmacy’s voice mail system for what sounded like “zolpidem” 100 mg, take four tablets by mouth once daily. A licensed pharmacy intern retrieved the prescription from the voice mail system and knew this was a strange dosage strength and dose for this hypnotic agent used to treat insomnia. The pharmacy contacted the physician to clarify the prescription. It turns out that the physician intended the patient to receive Zyloprim (allopurinol) for gout. To prevent mix-ups such as this, prescribers should spell out the drug name and sound out the dose (such as, one–five instead of fifteen), provide the indication, and use both brand and generic names when prescribing these drugs. Pharmacies should record information on their outgoing voice mail messages to prompt prescribers to provide this information.

PREVENT UNINTENTIONAL MEDICATION OVERDOSES

An outreach worker visited the home of a patient with active tuberculosis to administer a dose of the oral antitubercular agent isoniazid to the patient’s 2- and 4-year-old children. After administering approximately one-half of the dose to the 2-year-old, the child vomited. The syringe containing the remainder of the dose was laid down on a table while the child was cleaned. The 4-year-old child, who had already received his dose of medication, picked up the unsecured syringe and ingested the remainder of the medication. As a result, he received approximately 800 mg of isoniazid total. Thankfully, the child

Continued on page 55 ➤

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Continued on page 55 ➤
PCCA has joined the National Community Pharmacists Association in a fundraising campaign to help raise $50,000 for the NCPA Foundation by the end of 2013.

PCCA will match individual donations made directly to the NCPA Foundation by December 31, 2013.*

**NCPA Foundation: Donation Form**

- **TODAY’S DATE**
- **NAME**
- **PHARMACY/COMPANY NAME**
- **ADDRESS**
- **CITY**  **STATE**  **ZIP**  **PHONE**
- **DONATION**  $1,000  $500  $250  $150  Other $ 

**PAYMENT**
- ☑ Credit Card
  - American Express  Discover  MasterCard  Visa
- ☐ Check

Enclosed is my check payable to the NCPA Foundation for $ ____________

Return this form by fax to 703-995-0344; mail to NCPA Foundation, 100 Daingerfield Rd, Alexandria VA, 22314; or visit www.ncpafoundation.org to make a donation.

*PCCA will match designated NCPA pre-convention program registrations at the 2013 NCPA Annual Convention and individual donations through 2013—up to a combined total of $50,000.

About the NCPA Foundation: Donor support helps the NCPA Foundation preserve the legacy of independent pharmacy through scholarships to pharmacy students, research/programs to improve the success of independent pharmacy and patient care, community health awareness programs, and aid to community pharmacy owners for their recovery in the event of disaster or other adverse circumstances. The foundation was established in 1953 and is a non-profit 501(c)(3) organization. Contributions are tax-deductible as charitable donations to the extent permitted under federal tax law. Visit www.ncpafoundation.org.

*PCCA will match designated NCPA pre-convention program registrations at the 2013 NCPA Annual Convention and individual donations through 2013—up to a combined total of $50,000.
Complete this form online at www.Fight4Rx.org or mail to: National Community Pharmacists Association Attn: Michael Rule 100 Daingerfield Road Alexandria, VA 22314 703-683-3619 fax

Fight4Rx Patient Newsletter Form

NAME

PHARMACY

ADDRESS

CITY/STATE/ZIP

PHONE FAX E-MAIL

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Thank you for your participation!

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Your patients know firsthand the valuable role you play in their health care. Their voices are critically important to policymakers in understanding that role and the services you provide to the community. Ask your patients to stay informed on issues affecting their pharmacy choice by signing up for a bimonthly newsletter and action alerts from Fight4Rx. Simply have them fill out the form below and return to NCPA, or they can register online at www.Fight4Rx.org.

PATIENT CALL TO ACTION!
PATIENT CALL TO ACTION!
YOUR PATIENTS HAVE A STORY TO TELL! ASK THEM TO SHARE IT THROUGH FIGHT4RX™!

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Thank you for your participation!
Editor’s Note: For a list of references used in this article, please contact Chris Linville, managing editor of America’s Pharmacist, at chris.linville@ncpanet.org.
Methadone is most widely known for its use in detoxification and in maintenance treatment of opioid addiction. Increasingly, it has been used for the management of moderate to severe chronic pain, and for cancer-related pain that is unresponsive to high doses of conventional opioid analgesics. Although methadone was approved by the Food and Drug Administration for the management of pain in 1947, it was not widely used for this purpose until the latter part of the 20th century.

Recently, there has been a rise in reports of fatalities and adverse effects related to methadone toxicity. Due to its long half-life, unpredictable pharmacokinetics and lack of standardized equianalgesic conversion ratios for chronic use, methadone should only be managed by health care professionals who are familiar with the drug, or under the supervision of pain-management specialists.

Despite methadone’s potential for toxicity, its unique characteristics make it a favorable choice for pain control. Methadone is inexpensive, long-acting, has high oral bioavailability, is available in numerous dosage forms and has no active metabolites. Along with relieving neuropathic pain, its antagonism at the N-methyl-D-aspartate (NMDA) receptor may also prevent the buildup of opioid tolerance.

To utilize methadone both safely and effectively in patients, it is important to have a good understanding of its pharmacology, available dosage forms, pharmacokinetics, pharmacodynamics, and dosing strategies.
Pharmacology
Methadone is a lipophilic, synthetic μ-, δ- and κ-opioid receptor agonist and a NMDA receptor antagonist. While having a weak affinity to both the δ- and κ-opioid receptors, methadone has a greater affinity to μ-opioid receptors when compared with morphine. It exhibits its analgesic activity by altering the pain response through inhibiting ascending pain pathways in the central nervous system. Its action at the NMDA receptor is believed to provide neuropathic pain relief and reduce opioid tolerance. Methadone has also been found to inhibit the reuptake of serotonin and norepinephrine in the descending pain pathway, providing additional analgesic effects.

Dosage Forms
In the United States, methadone is manufactured as a racemic mixture of two stereoisomers, L-methadone and D-methadone. It is available as an oral tablet (5 mg, 10 mg), oral dispersible tablet (40 mg), oral solution (5 mg/5 mL, 10 mg/5 mL, 10 mg/mL) and injectable solution (10 mg/mL). Since 2008, access to the 40 mg dispersible tablet has been restricted to hospitals and facilities authorized for the detoxification and maintenance treatment of opioid addiction. It is important for clinicians to recognize a compounding pharmacist’s ability to provide medications in alternate dosage forms for different routes of administration. Methadone has been extemporaneously compounded into topical gels, transdermal gels, suppositories, and concentrated liquids. Coyle et al showed that 50-70 percent of cancer patients will require alternate routes of administration during their last few months of life, as a result of altered mental status, neuromuscular dysfunction, nausea and vomiting, the inability to swallow, bowel obstruction or malabsorption.

Pharmacokinetics
Due to methadone’s high inter-individual variability in absorption and metabolism, it is essential to be familiar with methadone’s pharmacokinetics. Methadone’s oral bioavailability is approximately 80 percent, making it more favorable than other opioids when administered orally. Drug levels are detected in the plasma in about 30 minutes, and peak plasma levels are reached in 1 to 7.5 hours, providing rapid relief of acute pain.

The apparent volume of distribution for methadone is large, due to its lipophilicity. Methadone has a small, central plasma compartment, which is in equilibrium with a larger tissue compartment. When absorbed, only about 2 percent of drug remains in the plasma. About 98 percent of methadone accumulates in the tissue compartment, which includes the liver, kidneys, lungs and the brain.

Methadone’s plasma concentrations are said to follow a bi-exponential curve over time. It includes a rapid α-phase (movement from the central to tissue compartment) and a slow β-phase (elimination of methadone accumulated in tissues). The half-life of the rapid β-phase can range from 1.9 to 4.2 hours, and the half-life of the slow β-phase can range from 8.5 to 47 hours. As a result of this variability and long half-life, pain evaluations should be conducted frequently, and dosing should be adjusted appropriately during maintenance treatment.

Methadone is metabolized both in the liver and the small intestine by Cytochrome P450 (CYP). The major isoenzymes are CYP3A4, CYP2B6, CYP2C19, CYP2C9 and CYP2D6. It undergoes N-demethylation, and is converted to its inactive metabolite, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP).

Methadone as an unmodified drug, EDDP and various other inactive metabolites are eliminated through the kidneys (15-60 percent) and feces (20-40 percent). When the urine is more basic in pH, the kidneys more readily reabsorb methadone molecules, reentering them into circulation. Urine acidification, on the other hand, leads to increased excretion of the drug. Thus, urinary pH changes can cause variations in elimination rate, half-life and apparent volumes of distribution.

Pharmacodynamics
The rise in reports of fatalities and adverse effects related to methadone are most likely associated with methadone’s potential for toxicity. Methadone has a black box warning for respiratory depression and a risk of QT segment prolongation—both of which can lead to death. The former occurs when the body’s natural drive to re-commence respiration is diminished. The latter can lead to a potentially fatal polymorphic ventricular tachycardia called torsades de pointes. A normal value for a corrected QT interval (QTc) ranges from 390 to
Table 1: Common Substrates, Inducers and Inhibitors of Three Major CYP450 Isoform Metabolizers of Methadone

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420 msec and 400 to 440 msec for men and women, respectively. Drug-induced torsades is associated with a QTc greater than or equal to 500 msec. When co-administered with medications known to prolong the QT interval, the risk for torsades can be increased, so a thorough medication review should be conducted prior to considering methadone.

In a retrospective study, Krantz et al found a positive relationship between methadone dose and the occurrence of torsades. Co-administration of medications that inhibit or are substrates of CYP3A4, CYP2B6, CYP2C19, CYP2C9 and CYP2D6 can increase methadone toxicity by tying up these enzymes and slowing down methadone metabolism. The opposite effect may occur when co-administered with inducers of these isoenzymes, causing increased pain perception or withdrawal symptoms.

Interindividual variability in CYP450 isoform activity due to genetic polymorphisms has also been shown to affect the metabolism of methadone. Table 1 shows a list of substrates, inducers and inhibitors of the three major CYP450 isoforms that metabolize methadone. When taking these medications concomitantly with methadone, caution should be advised.

**Methadone Dosing**

*Methadone Dosing for Opioid-Naïve Patients*

Typically methadone is not prescribed by physicians as a first line pain medication in opioid-naïve patients. However, it may have multiple benefits depending on each patient’s situation and the underlying cause of pain or disease state. For instance, a patient who is experiencing diabetic neuropathy, chronic pain, and who may not be able to afford more expensive medications may potentially be a prime candidate. Methadone has been shown to be safe and usually well tolerated at 2.5 mg every eight hours. A practical starting dose of methadone is 5 mg every eight hours, with dose increments of 5 mg every eight hours every five to seven days. However, in patients 65 years and older, doses as low as 2.5 mg daily may be required due to diminished methadone clearance. Faster titration may be more appropriate for patients with cancer pain and where frequent physician monitoring is readily accessible. According to the Veteran’s Affairs/Department of Defense
Clinical Practice Guidelines, a faster titration protocol is available, recommending 2.5 mg every six to eight hours, with 2.5 mg increases every six to eight hours as often as every day over about four days.

Patients receiving a scheduled dose of methadone also need the availability of an “as needed” pain medication in the event of breakthrough pain. During this time it is recommended that patients be monitored weekly during the titration phase, and then every one to two months during the maintenance phase. Due to methadone’s wide variability in pharmacokinetics and pharmacodynamics, dosage titrations should typically occur every five to seven days until adequate pain control is achieved, unless undergoing a faster titration phase.

**Methadone Dosing for Opioid-Tolerant Patients**
Calculating equianalgesic doses for methadone can prove to be difficult and sometimes confusing. An equianalgesic dose conversion to methadone from other opioids should be performed in two steps. Because morphine to methadone comparisons have been the most widely studied, the first step is to convert the patient’s current opioid regimen to a daily oral morphine equivalent dose. The calculated dose should include all long-acting and short-acting opioid doses.

After conversion to daily oral morphine equivalents, the second step is to use a conversion ratio to determine the new methadone dose. One important difference regarding methadone conversion tables is the absence of a single ratio for converting morphine to methadone. It is important to note that with repeated dosing, methadone’s analgesic potency increases, and the majority of published equianalgesic charts do not take into account variations in potency that may exist with the accumulation of multiple doses. Numerous analgesic charts indicate that 15 mg of morphine is approximately equivalent to 10 mg of methadone. As the total daily amount of morphine increases, the conversion ratio changes considerably. Inappropriate dose conversions can potentially lead to an overdose in patients resulting in respiratory depression or death.

Table 2 outlines multiple models for converting methadone to morphine with a wide variety of differences amongst conversions. Currently there is no one model considered most appropriate.

Ripamonti et al published the first methadone conversion strategy in 1998. Ripamonti’s method reduced the daily oral morphine equivalent dose by at least 30 percent over the first 24 hours. The decreased morphine dose was then replaced with methadone given every eight hours, according to the ratio corresponding with the patient’s current daily morphine dose. On the second day, if the patient’s pain was adequately controlled then the morphine dose was decreased again, and the methadone was only increased if the patient experienced moderate-to-severe pain. During the third day of the study, morphine was discontinued and patients were managed on methadone given every day.

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**Table 2. Comparison of Proposed Morphine to Methadone Conversion Parameters**

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<td>Morphine dose (mg/d)</td>
<td>30 – 90</td>
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<td>Morphine: Methadone EDR</td>
<td>3.70:1</td>
<td>7.75:1</td>
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<td>101 – 300</td>
<td>301 – 600</td>
<td>601 – 800</td>
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<tr>
<td>Morphine: Methadone EDR</td>
<td>3:1</td>
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<td>Morphine: Methadone EDR</td>
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<td>Methadone (mg) =</td>
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eight hours with the addition of 10 percent of the daily methadone dose given as an additional dose for breakthrough pain. Methadone was continually titrated until patients received adequate relief.

Conversion ratio determination was made by classification of daily oral morphine equivalent doses into three groups or breakpoints: 30-90 mg, 90-300 mg, and 300 mg or more. Limitations of this study include small sample size (n=38), narrow inclusion criteria (predominately cancer-related pain patients), and most notably, equianalgesic dose ratio breakpoints that create dosage swings that appear as peaks and troughs when graphically represented. For example:

Patient A: Morphine 90 mg/day = would require 24 mg/day of Methadone
Patient B: Morphine 105 mg/day = would require 13.5 mg/day of Methadone

One would not expect a dose of methadone to decrease if the total morphine dose has increased, but due to the stratification of dose breakpoints into three groups, it occurs when a patient’s dose approaches the extremes of each range.

In response to the lack of well-studied equipotent ratios, Ayonrinde’s protocol further stratified the daily oral morphine equivalent doses into six groups. Once the ratio was identified and the methadone dose calculated, the original opioid was discontinued and methadone was started. A loading dose consisting of 25-50 percent extra methadone was used on the first two days of therapy in order to saturate the body’s tissues. The protocol used initial dosing intervals of every six hours, and over several days extended the intervals up to eight or twelve hours.

By providing six different breakpoints for the total daily dose of morphine, Ayonrinde’s proposed conversion ratios may appear to provide more accurate methadone doses, but this method actually has the greatest dosage swings at each breakpoint. In addition to this shortcoming, Ayonrinde’s protocol utilizes the least conservative ratios of the methods examined in this article. This study suffers from an even smaller
Help Your Fellow Pharmacist

The NCPA Foundation continues to assist independent community pharmacies across the nation damaged by tornadoes, flooding, and destructive storms thanks to donations to the Disaster Relief Fund.

Be sure to download the Disaster Preparedness Checklist on the disaster relief page of www.ncpafoundation.org, where you’ll find useful tips to help you reduce the consequences of an unexpected event.

If you haven’t made a donation . . . please donate today! And if you already have, your generosity is deeply appreciated!

Through donor support, the NCPA Foundation preserves the legacy of independent community pharmacy through scholarships to pharmacy students, research and programs to improve the success of independent pharmacy, community pharmacy-based health awareness programs, and aid to community pharmacy owners for their recovery in the event of disaster, illness, or other adverse circumstances.

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“We have been around pharmacy for years and we learned more in these past few days than we ever imagined!”
— Jill and Fred S., Hamilton, AL

“Gabe Trahan gave me some great advice and I am ready to start implementing it in my pharmacy.”
— Micaela Riemer, PharmD., Cave City Prescription Center, Inc., Cave City, KY

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sample size (n=14) than Ripamonti, and 13 of the 14 participants suffered from neuropathic pain.

The largest study was conducted by Mercadante et al, who proposed ratios based on the treatment of 52 patients in palliative care units. Patients stopped receiving morphine and were immediately switched to methadone based on the conversion guidelines found by Ripamonti et al. Methadone was given every eight hours and one-sixth of the total daily dose was used as a rescue dose that could be administered up to three times per day. Titration of methadone doses was based on the patient’s use of rescue doses. Because the conversion ratios used were very similar to ratios used by Ripamonti’s group, graphically represented morphine to methadone conversion ratios resulted in superimposed lines. Consequently, this study suffers from the same dosing anomalies near the oral morphine equivalent dose breakpoints. Like previous studies, Mercadante et al’s study was limited by its small sample size (n=52) and the patient inclusion criteria (mostly lung cancer patients).

In an effort to better represent doses that are near previously proposed breakpoints, Fudin has derived a mathematical model to create a “line of best fit” which aims to produce a continuous and fluid curve. The new curved line decreases peaks and troughs at dose interval breaks, maintains conservative dosing, and reconciles the Ripamonti, Ayonrinde, and Mercadante doses for patients with daily oral morphine equivalents exceeding 300 mg per day. Finally, because Fudin’s equation is based on results from the previously mentioned studies, the limitations of those studies (such as sample size, homogeneous inclusion criteria) are inherent in the Fudin formula. Practical Pain Management has recently developed an online calculator that calculates methadone equivalencies using Fudin’s formula. The calculator can be accessed online at (http://opioidcalculator.practicalpainmanagement.com/). We suspect that over time with continued application and additional studies, clinicians will have more confidence when converting to methadone.

**Practical Application**

As one can see, the previously listed protocols suffer from inherent flaws and inconsistencies, including a variety of methadone to morphine conversion ratios. Due to this, pharmacists must take care not to underdose or overdose patients when converting to methadone from other opioid analgesics. Careful dose selection and patient monitoring are necessary, particularly in the first few days after converting a patient to a methadone regimen. Clinicians must take into account additional variables that can affect dosing, such as the patient’s current opioid regimen and perceived pain scores. For example, if a patient is experiencing uncontrolled pain, use of a 6:1 rather than a 10:1 ratio may be necessary. Daily monitoring of pain scores, number of breakthrough medications, and adverse effects (such as respiratory rate) should be performed. Pharmacist should also recommend an “as needed” instant release opioid dose equal to 10-15 percent of the total daily dose of methadone, which is given every three to four hours as needed in the event of “breakthrough pain.”

Despite methadone’s stigma of only being used in patients experiencing withdrawal symptoms from drug abuse, when used appropriately, methadone can be an excellent pharmacoeconomic option for treating pain. Methadone is relatively inexpensive when compared with other opioid analgesics, has a long half-life, and has excellent oral bioavailability. Methadone’s multiple mechanisms of action allow it to be used to control visceral, somatic, and neuropathic pain, as well as to help decrease tolerance. Methadone’s unique characteristics give practitioners the ability to use an opioid to treat multiple pain symptoms. As methadone use continues to rise, further studies are needed to identify a universal dosing protocol in order for clinicians to have a concrete standard of practice. Increasing acceptance of methadone use for pain management has made it necessary for practitioners to be aware of the complexity associated with it and the need to consult a pain management specialist if they are not experienced in prescribing methadone.

Yoon Joo Lee, PharmD, is a pharmacist at Comfort Care Pharmacy, Del City, Okla.

Joshua R. Sheffield, PharmD, is co-owner and pharmacist in charge at Comfort Care Pharmacy and clinical assistant professor at the University of Oklahoma College of Pharmacy.

Manuel A. Calvin is a 2014 PharmD candidate at the University of Oklahoma College of Pharmacy.
Prescription Parlour Pharmacy in the Bahamas goes the extra mile, 24 hours, seven days a week

by Chris Linville

Mention the Bahamas, and many thoughts might come to mind: bright sunshine, warm breezes, clear blue seas, beautiful beaches, and perhaps a cold tropical drink in your hand.

While those images may be accurate, the Bahamas is much, much more than simply a vacation destination. People live, work, and raise their families there. And when they need health care, Prescription Parlour Pharmacy in Nassau is available 24 hours a day, seven days a week.

“Our superior customer service is what sets us apart from the competition,” says NCPA member Laura Pratt-Charlton, BPharm, Prescription Parlour’s director of pharmacy services. “Our mottos are ‘Efficient, Professional Service Guaranteed,’ and ‘Come let us pamper you back to good health.’ We want to ensure that all customers are afforded an opportunity, through our services, to enjoy the benefits of optimal mental and physical health.”

Laura owns the pharmacy, which celebrated its 20th anniversary in August, with her husband David Charlton, who serves as director of OTC and finance. Their
8,000-square-foot facility has a dispensary and front-end section which has a variety of products, including OTC medicines; health and beauty items; groceries; personal care products; vitamins and supplements; home health care accessories; sexual wellness items; household goods; childcare aids; diet and fitness products; and a small electronics section. The pharmacy, with more than 40 on staff (full and part time), also provides passport photo services and prints banners and posters.

The Charltons say that among their OTC offerings, grocery, cough and cold, pain management, and vitamins and supplements are their biggest sellers. They plan on expanding their selections by adding seasonal toys and more electronics.

It is this broad range of products and services that the Charltons believe set Prescription Parlour apart from the competition.

“I often say to the staff that all the other pharmacies are offering the same products, but it is the quality of service given to the patients that will distinguish one from the other,” Laura says. “Our customers appreciate that we exist to provide them with professional and convenient service by a complement of well trained, friendly and proficient staff to ensure their optimal good health 24-7. Our location in a densely populated community and the variety of services and products offered is also a benefit to the community.”

Along with running a successful business, in their “spare” time, the Charltons are heavily involved in track and field, with David coaching the Olympic gold medal-winning relay team at the 2012 games in London. (See sidebar.)

**Pharmacy Growth**

The Bahamas (officially the Commonwealth of the Bahamas) is an archipelago of approximately 700 flat, low-lying islands in the Atlantic Ocean, extending from about 50 miles east of Florida to 50 miles northeast of Cuba. Although the total land area of the archipelago is approximately 8,500 square miles, slightly larger than New Jersey and Connecticut combined, the islands are sprawled over an area of approximately 158,000 square miles.

New Providence Island is home to Nassau, the Bahamas’ capital, largest city, and commercial center. With 250,000 residents, it has 70 percent of the country’s population.
Both Laura and David are Bahamas natives. Laura was born on Long Island and grew up in Nassau. David was born on Mayaguana Island and raised in Grand Bahama, the northernmost of the chain.

Laura says that she had an interest in health care from a young age, and initially wanted to study medicine. In pharmacy school, she learned more about the business side of the profession, speaking with pharmacists who expressed their job satisfaction.

“I also realized that I was not fond of the sight of blood and not truly thrilled with the vertebrate dissections,” she points out.

Laura and David both attended Howard University in Washington D.C. She received her BPharm degree in 1988, while David graduated with a degree in mechanical engineering.

After finishing school, Laura returned to the Bahamas and worked for a community pharmacy as assistant head pharmacist, managing three of its locations in New Providence. In 1993, she and David decided to strike out on their own with Prescription Parlour Pharmacy. She says the business was founded based on her “passion to become an entrepreneur and to be an innovator in the pharmacy industry in the Bahamas.”

The pharmacy was a modest 300-square-foot “cubby hole” when it opened in August 1993. Two years later, Prescription Parlour moved to a 1,100-square-foot location a block from the old store. In 1996, the Charltons say it became the Bahamas’ first and only 24-hour pharmacy.

In February 1999, the pharmacy opened a branch in the western end of Grand Bahama Island. Prior to that, residents had to drive a considerable distance to the town of Freeport to obtain prescription medications.

In 2003, continued growth prompted another expansion to another location with about 2,000 square feet. In November 2009, Prescription Parlour moved to its current building. With 8,000 square feet at their disposal, the Charltons added an extensive front end with a convenience store, intended to create a “one-stop-shop” for its customers. To help design the front end, they enlisted the services of Gabe Trahan, NCPA’s senior director of store operations and marketing.

“We were totally fascinated by his insight, knowledge and passion,” David says. “We engaged his services to advise us initially on floor planning then with merchandising.”

-CL
An entrepreneurial spirit and passion for innovation in pharmacy helped Laura Pratt-Charlton and her husband David build a successful business.

Convenience for Customers
Being a 24-7 business allows customers to come late at night or early in the morning for prescription medications and OTC items. Obviously, this setup requires planning for both staffing and security.

“There several eight-hour shifts between 7 a.m. and 11 p.m. for the pharmacy,” Laura says. “During the hours of 7 a.m. and 11 p.m. the pharmacy operates with pharmacists, technicians, cashiers, and security staff. However, between 11 p.m. and 7 a.m. the pharmacy operates with only a pharmacist and a security officer, and customers are not allowed entry into the main pharmacy after 11 p.m. The customers are served from an enclosed foyer area with a speaker and private phone for communication and a metal drawer for delivery of medication and OTC items.”

The Charltons says for the most part that pharmacy practice in the Bahamas is similar to that in the United States. The major difference, they say, is that “We only have Bahamian-owned community pharmacies, so there are no ‘big chains’ crushing the independent pharmacies. The majority of our business is ‘cash and carry’ with limited third party claims. And we do have a national prescription drug plan [National Prescription Drug Plan].”

The NDBP was created in 2009 to improve access to prescription drugs and medical supplies in public and private pharmacies for chronic disease patients, and to provide funding for health promotion and wellness projects that are focused on reducing the numbers of Bahamians affected by targeted chronic non-communicable diseases. According to the Bahamas government, one out of every three Bahamians suffers from chronic non-communicable diseases, which are difficult to control and have a major impact on the quality of life of those affected.

Looking ahead, the Charltons don’t plan on sitting still. “We intend to develop an aggressive marketing plan to expand the compounding services,” Laura says. “We will be starting a diabetes center to offer testing, counseling, monitoring, training, and education, with full-line home health care solutions. The program will be affiliated with other regional [Caribbean] organizations with the headquarters in Barbados, and structured by the Diabetes Foundation. We also plan to open two more pharmacy branches in New Providence.”

Asked for their views on the state of independent pharmacy, the Charltons say that innovation must be at the forefront.

“To remain successful in the industry, community pharmacies must stay on the ‘cutting edge’ and be prepared to think outside of the box and offer services that only independent pharmacists can offer,” Laura says, citing services such as medication therapy management, compounding, and immunization programs. “These and other value-added services can help retain your customers and bring new business to your pharmacy with the focus on creating a ‘healthier consumer’.”

Trahan has seen firsthand the personal touch and care that the Charltons show toward their customers. “Many times I have witnessed Laura come out from behind the bench and hold and comfort a sick infant while quietly consulting with the child’s mom,” he says. “I never seen so much genuine compassion offered to a customer. David and Laura are humble people; it is simply an honor to know them.”

Chris Linville is managing editor of America’s Pharmacist.
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Synchronizing technology seamlessly is the key for providers and patients

By Bill G. Felkey

If you were asked to choose either integration or connectivity, most people would probably respond either, "I want both!" or "What's the difference?" Actually, connectivity is usually the precursor to integration. Integration occurs when all possible subsystems, computers or components are linked physically or functionally for seamless operation. In a perfect world this linking occurs in real time or near real time. Health care technology across all disciplines and specialties in general and in the pharmacy specifically, ideally, needs to be fully integrated to allow an efficient, effective, safe, and timely flow of information in support of patient care services and clinical decision making. All of us have probably had experience with systems that are not integrated. Many have scars they can show from the problems that ensue when this is the case. System integration or interoperability remains one of our biggest challenges and goals regarding health care.

Perhaps you purchased an interactive voice response system (IVR) that was not integrated to your pharmacy management system (PMS). When a system is not integrated, I call this the Bubba link. Someone named Bubba (or Sally or Fred) has to look on one screen and input the information from that screen on to another screen. This is not only wasteful in terms of time but it also introduces an opportunity for errors to occur. Point-to-point interfaces are the next level of connectivity moving toward integration. These interfaces can be either one directional or bidirectional in design. Of course, bidirectional interfaces are preferred because two systems are able to exchange information instead of just one system being able to send messages to the other. By the way, Health Level Seven International (HL-7) (http://www.hl7.org/) is an organization that develops standards for how these messages are formatted when interfacing or integrating disparate systems.

A common example of an interface occurs between
the pharmacy management system and a dispensing robot. A one-way interface occurs when the pharmacy management system acts like it is sending a print file to a printer. Instead of printing, the robot interprets the text as a command and dispenses a properly labeled vial of oral solids. A bidirectional interface could send messages back to the pharmacy management system to indicate when a dispensing cell would require refilling or perhaps it could generate an order message to the pharmacy wholesaler when order points are reached in a perpetual inventory system. Complicated systems may require something called an interface engine. This is a computer that acts as a hub for all messages transferred between all subsystems. In essence, it takes every subsystem that speaks different languages and translates and reformats those languages into what each other subsystem needs to see to operate properly. Interface engines are commonly used in hospitals but the pharmacy management system usually serves as the hub system for community pharmacies.

**Fully Integrated IVR**
Consider how a fully integrated IVR would operate across a health care system. Patients would use their preferred device (telephone touchpad, computer browser, smart phone app, etc.) and request a refill of their blood pressure medication. The IVR would connect to the pharmacy management system and query whether refills were available from the prescription. If yes, the dispensing process would be queued and pending pharmacist verification, the pharmacy robot would prepare the vial for final inspection. The patient would be notified when to expect the medication to be ready. If all available refills had been utilized, the patient would be informed that physician authorization must be sought and notice of the medication availability would be sent by the patient’s preferred channel (text message, email, or recorded telephone call, to name a few).

Meanwhile, the PMS then initiates an electronic refill authorization request to the prescriber. On the prescriber’s side, this message triggers a check of the prescriber’s electronic medical record (EMR) to determine if the patient is overdue on an office visit or could record adherence data sent from the pharmacy to be used in the next episode of care by the physician. When and if authorized, the pharmacy system begins the dispensing process and the IVR notifies the patient...
as to when the medication will become available. There are about 20 things that would take place inside and outside of the involved subsystems in this transaction but thankfully they are integrated processes within each of the subsystems involved.

I want to walk you through a couple of critical connectivity pieces that need to be solved for pharmacists to remain fully viable and relevant members of the overall health care system in their communities. At present, hospitals are mostly using EHRs that have poor connectivity to employed and affiliated physician EMRs. These two entities have relatively poor or nonexistent connectivity to community pharmacies. Hospitals are universally performing medication reconciliation upon patient admission, transfer, and discharge. There is an opportunity for connectivity and eventual integration to occur in each and every patient "handoff" as we strive to achieve meaningful continuity of care in this process.

**HIE, CCD, and CCR**

Because the hospitals, physicians, and pharmacists I just mentioned are seldom truly integrated, there are a few processes that you ought to be aware of to optimize your care provision while we are waiting for integration to occur. Health information exchange (HIE) is getting renewed emphasis and funding from the federal government. HIE has the goal of moving protected health information between patient care providers in a timely manner to improve patient care processes. One way for these data to be exchanged is occurring through a continuity of care document (CCD) that combined an HL-7 formatted message with another standard-setting organization’s continuity of care record (CCR). Even though the CCD is considered a document, it comes in an electronic form that is “data scrapable,” which means that a computer system can take the data from the CCD and place it properly in the pharmacy management system for your use.

For example, upon discharge from the hospital, a CCD containing the discharge medications for patients can be sent to both the ambulatory care physician and pharmacist who will be caring for the patients going forward. This method is considered an interim means for health information exchange while we are waiting for greater levels of integration to occur. Pharmacy has a consortium of stakeholders trying to assure that the structure of the pharmacist electronic medical record is built to allow future integration at the highest possible levels. Your pharmacy management system vendor will need to closely monitor how processing of CCD data and eventual integration with standardized electronic health record data will occur.

**Patient Role**

Where is the patient in all of this? Have you heard of the Blue Button (http://www.healthit.gov/bluebutton) that was first offered by the Veterans Administration for its patients and is now being adopted by many other vendors? It allows patients to click on a blue button on their personal health record (PHR) and it downloads all of their notes from their health-care providers in a simple text format into their PHR. This text is not in a CCD format but is made for sharing information with patients and their nonprofessional caregivers. Remember that patients can give you access to the information on their PHR and can authorize your accessing any other resource being used to store their protected health information. Ready access to diagnoses, laboratories, and other data can start with patients.

There is one another connectivity option worth mentioning. Many hospitals are creating both provider and patient portals. These are web-based access points to be made of applications used by a health system, and include a private label branded personal health record for storing information that is available for patient viewing. I recommend investigating getting access to both of these portals to enhance your practice. Your pharmacy management system vendor could also, at some point, help you post relevant patient data that you house as a quid pro quo. There is so much more going on behind the scenes than I have space to write about in this article. You may want to look at a glossary of other terminology surrounding interoperability. One example of this type of glossary can be found at: http://www.corepointhealth.com/resource-center/healthcare-interoperability-glossary. As always, feel free to ask questions or make comments by email at felkebg@auburn.edu.

Bill G. Felkey is professor emeritus of Healthcare Informatics at Auburn University’s Harrison School of Pharmacy, Auburn, Ala.
Steve Rodriguez beat the odds in becoming a multi-pharmacy owner. Now he’s helping others in need

By Chris Linville

A few years after Steve Rodriguez, PharmD, opened MedPro Pharmacy (www.medpropharmacy.com) in Melissa, Texas, he had his eye on another location in nearby Plano, in suburban Dallas. In his mind it was an opportunity to provide pharmacy care for a predominately Hispanic population, a segment he says was being underserved in the area.

“With the Hispanic population there’s a lot of issues, particularly diabetes,” he says. “Much of it is because of a lack of education, so their health suffers.”

It’s a problem that hits close to home for Rodriguez, who overcame what he describes as a “rough upbringing” to become an independent pharmacy owner.

Rodriguez’s father, a native of Mexico moved to Texas at age 16. Rodriguez was born in Texas and moved around the state as his father sought jobs. As a kid in the 1980s, his father worked in the oil fields. When that industry went bust, he would be without work for months at a time, and the family lost their home. They then moved to Austin, where his father got a job in construction.

Reflecting on that period, Rodriguez recalled looking at his future.

“It was a tough time,” he says. “I was around 10 or 11 years old, and I decided then that whatever I do with my life, I want to be in position where I don’t have to worry about a job.”

As a youngsters, Rodriguez had always had an affinity for math, science, and chemistry. He recalls visiting a local pharmacy and being intrigued.

“I always wondered what they were doing back there,” he says. “Do they have some magic potion they are mixing? I was just fascinated.”

For a while Rodriguez also thought he wanted to be a pilot. But at the time he was living with an aunt and uncle, and his aunt, who didn’t fly, was not thrilled about the idea. When he mentioned pharmacy, she was much more supportive. “I think she was mostly just glad I didn’t want to be a pilot anymore,” he says with a laugh.

From that point, he focused his attention on pharmacy. Rodriguez enrolled at Angelo State University, where he played football for a few years and took pre-pharmacy courses. He then moved on to pharmacy school at Texas Tech University, where he received his degree in 2001.
“I’m one of a handful in my family to graduate from high school and the very first to go to a major university, much less graduate with a doctorate,” he says.

**Ownership Thoughts Never Far Off**

During his pharmacy studies, the idea of ownership never strayed far from Rodriguez’s thoughts.

“I came from a family of entrepreneurs,” he says. “My grandfather in Mexico had a bar, and my dad opened up a pool hall when I started in college, so I would work for him on the weekends and kind of run the shop. Later on he got into the dump truck business, and had his own trucks.”

During school, Rodriguez took business-oriented electives. After graduation, he worked for a number of independents, soaking up as much knowledge as possible.

“I learned what to do and what not to do,” he says. “I worked in all over Texas, spent time in the Dallas area, on the Gulf Coast, did some retail, and some hospital. I was trying to be the most well-rounded pharmacist I could be and learn as much as I could.”

After a few false starts in his ownership efforts, Rodriguez saw his dream realized when he opened his first MedPro Pharmacy in August 2006. Along with prescriptions, its offerings include compounding, assisted living, clinical programs, immunization, cholesterol screening, and diabetes screening, just to name several. Between the two stores Rodriguez has one full-time pharmacist, two part-time pharmacists, four full-time clerks, an office manager, clinical coordinator, and several clerks. He is active in social media with a Facebook page and Twitter account.

It wasn’t until after opening his pharmacy that Rodriguez realized that his business was making a difference in people’s lives.

“It’s not until you sign that first paycheck for an employee, or pay that first drug bill, that things really start to sink in [about ownership],” he says. “It’s like, ‘whoa,’ the decisions that you make impact not only you and your family, but it impacts the community. As community pharmacist, the community looks to you as a leader. They know you have influence. The community will look to you, and I think you have to embrace those opportunities. You have to give back.”

And that’s what he’s tried to do. Rodriguez has served as chairman of the board for the local chamber of
commerce, as treasurer for the economic development board, and co-chairman for a committee advocating to have a charter to run the town as its own entity. He coaches his son’s soccer team, and sponsors local booster clubs and school organizations.

“Those are just the things that independent pharmacies do,” he says.

**Second Pharmacy—Serving a Need**

Around the time he was ready to open his second location, Rodriguez was put in touch with Live Oak Bank.

“I got in touch with them [LOB] through a headhunter,” he says. “I don’t normally take those calls, but had an eye on a second location in Plano and wanted to open there. They happened to call me when that location came up. I thought, ‘Why not?’ I already had an outstanding loan on my Melissa store, so didn’t think it would work out. But they said not only would they buy the loan out, but they would also finance the new location.

“Having a partnership like that is priceless,” he says. “The relationship, the value and the opportunities that Live Oak Bank provides for independent pharmacy is just tremendous.”

With the opening of the Plano MedPro in 2012, Rodriguez says it was his way of “giving back, knowing where I came from and how I grew up.”

Rodriguez says his background helped him create a comfort zone with his patients. He tells the story of a man who came in with an eye irritation.

“He had gone to a couple of clinics and they said he had to make an appointment,” Rodriguez says. “He came to me asking for help. We went to the back of the pharmacy, to a sink, I put my gloves on, and I discovered he had a small piece of wood in his eye. Had I not done that, that guy would have ended up in the emergency room. It’s things like that where independent pharmacists save the health care system so much money.”

Taking extra time to help people such as that patient builds bonds. But as Rodriguez says, “That’s just human nature. People like to do business with people they know, like, and trust. Once they get to know you, they get to like you. And once that happens, they trust you. That’s how you get a customer for life. That’s how you build your business.”

**Political Advocacy**

The NCPA political action committee’s motto is motto says, “Get into politics or get out of pharmacy.” And Rodriguez has certainly gotten into politics in a big way.

“I’m heavily involved,” he says. “That’s one thing that is very, very important to the survival of our profession. Pharmacists have to be political and they have to be proactive. The days of sitting back and letting other people make decisions for you—those days are gone. If you want to stay in business you can’t do that.”

Rodriguez was extremely vocal in the debate surrounding the Express Scripts/Medco merger.

“I went to Washington and met with senators and representatives speaking out against the merger,” he says. “I said it was going to be bad, not only for independent pharmacy but the state of Texas.”

Rodriguez says knew someone personally who worked for Medco, and explains that when Express Scripts bought them out, she left, saying they were letting everybody go. “They are closing down facilities and offices and moving everything to St. Louis” he says. “I told my elected officials that jobs are being lost in Texas.”

Rodriguez created a video expressing his opposition to the merger that he posted on You Tube (MedPro Pharmacy.tx). He has also created several other videos about his pharmacy that are available on You Tube.

“I’m just trying to stay out there and be involved,” Rodriguez says. “I know that as pharmacists we don’t all agree on everything, but we all have to pull together and find common ground. We’re all on the same team. We just need to be involved.”

He cites the recent battle over compounding as especially critical. “If we don’t do something about, it [compounding] might go away.”

Still, despite the political challenges, Rodriguez says he is thankful that he had an opportunity to pursue a career in a profession that he loves. He points out, “If I can do this, anybody can. I had to overcome hurdles, and some people think it’s a miracle that I’m here. But I’m here now and I’m very proud to be an independent pharmacy owner. I love what I do, I love every day, embrace every day, and just constantly try to find ways to seek knowledge and make my pharmacy better.”

Chris Linville is managing editor of America’s Pharmacist.
Editor’s Note: “Profit Pearls” is an occasional series of articles focusing on pharmacies who have successfully used innovation, expanded offerings, and outstanding customer service to become staples of their community.
Recognizing a need and fulfilling it

By David Young

A distinguishing and common characteristic of independent pharmacists is the emphasis placed on patient care and overall patient satisfaction. The diverse population of people we see has wide-ranging needs that call for unique attention and understanding. Recognition of areas and populations of need is where pharmacist can make a difference. For Dorinda Martin, owner of Dripping Springs Pharmacy in Dripping Springs, Texas, the area of need was in women’s health and well-being. She has devoted herself to improving the quality of life of women who suffer with hormonal and other issues, and she has taken hormone replacement to the next level.

Throughout her life, Martin has made continuous efforts and contributions to advance pharmacy as a profession. She has been a pharmacist for 37 years and has seen all the different sides of the business. During her first years as a staff pharmacist, she began to recognize the role the pharmacist should play in patient adherence and safety. She took this, along with other self-taught lessons, and applied it to her future business endeavors. Martin and a colleague soon had the opportunity to buy two pharmacies, which they expanded to include long-term care. Here, Martin saw the need for consultation in the nursing homes and began developing ways to better monitor patient charts. She was soon seen as the local expert, which helped her business grow. Martin then sold the pharmacy and became a regional manager for six pharmacies before she was promoted to clinical director for the Texas operation in long-term care. She was inspired during this time to go back and obtain a PharmD degree. After almost 15 years of her time spent in LTC, Martin decided it was time to return to ownership. She and her husband Jim purchased a small independent pharmacy in Dripping Springs, where they saw the need for customized compounded medications. Their business has continued to grow and they have now expanded to include two additional stores (Lamar Plaza Drug Store and soon to open Lake Hills Pharmacy) in the Austin area.

Focus on Women’s Health

Martin focused the PharmD classes she took on women’s health, and she really wanted to integrate this into her pharmacy. She educated herself through as many avenues as possible, taking classes with PCCA, attending credentialed seminars, and reading materials produced by credible authors and A4M (American Academy of Anti-Aging Medicine). Hormone consultation is now a big part of

Left: Patient care and patient satisfaction is the primary focus for Dorinda Martin.
their business, and there is only one pharmacist on staff performing these consultations—Dorinda herself.

“I take hormones very seriously and have a healthy respect for what they can do,” Martin says. The consultations include a saliva test that gives a good idea of the hormone values at the tissue level, giving a reasonable baseline and starting point for recommendation of therapy. The patient also fills out a five-page form that documents a detailed medical history. Martin then reviews this information, and writes up a report which she then goes over with the patient at the consult. The report gives the patient an understanding of what all of the values are and what they mean. It also includes recommendations of options that should help replenish the hormone levels (based on their age, weight, lifestyle, history, current levels, etc.). She then writes up a recommendation and communicates with the patient’s physician. Her reports are taken seriously, as 99 percent of these recommendations are accepted by the doctor.

At Dripping Springs Pharmacy, the list of products it compounds is extensive, ranging from hormonal to veterinary compounds. With the hormonal medications, Martin likes to use the fewest drugs in the lowest effective amounts to achieve an improved life for her patients. She makes the patient aware of the role that each hormone can play in a woman’s well-being and that each medication is tailored to that patient’s individual needs. Close monitoring and frequent follow-ups help each patient reach her necessary hormonal levels safely and effectively.

Along with these compounds, Dripping Springs and Lamar Plaza pharmacies provide several other options that help with their patients’ (both women and men) overall health and wellness. The pharmacy staffs naturopathic doctors who offer a holistic approach to health care. Their expansive knowledge in alternative medicine helps them recommend a variety of pharmaceutical grade supplements and different herbal remedies.

**Skin Care Products**

Martin discovered that the patients’ self-image and need for feeling and looking younger was an important part of their overall health. With this in mind, she has helped develop their own line of over-the-counter skin care products, named “Dorinda James™” cosmeceuticals. Jim and Dorinda worked with anti-aging functional medicine doctors and a dermatologist to develop the formulas for the different applications, which include products that are involved in skin lightening/brightening, firming, cleansing, soothing, or a combination of these actions.

Martin is always looking for new ways to expand the services available to her patients. Other services their pharmacies offer include delivery, diabetes shoe fittings, immunizations, the Take Charge® (http://www.takechargerx.com/) weight loss program and consultations, lipid panels and A1C testing, and diabetes education classes. One of the few things they lack is a drive-thru, so they offer curbside/concierge service. Wherever there is a need, Martin is looking to fulfill it. When asked about future plans for the business, she says, “Keep on growing it. I just read an article by Warren Buffet where he said he was going to retire five years after he died. That’s about all I have in common with Mr. Buffet.”

When expanding a business, or even when just sustaining it, there is one thing that remains an absolute necessity for success, and that is lifelong learning. This is something Dorinda Martin has always practiced, and it has been very instrumental in her success.

“We may stop and start lots of projects, change to different jobs, and embark on other careers, but we always continue to learn,” she says. The future of pharmacy is as bright as ever, but it is going to require hard work and an open mind. Take a lesson from Martin, and take advantage of the resources available to expand your education. Your business and patients will see the rewards. eP

David Young is a 2014 PharmD candidate at the University of Houston College of Pharmacy.
Upon successful completion of this activity the pharmacist will be able to:
1. Describe the role that selected medications play and their effect on metabolic pathways.
2. Choose appropriate nutritional supplementation to offset drug-induced nutrient depletions.
3. Design a plan to develop a profitable nutritional niche by preventing drug-induced nutrient depletions.

Upon successful completion of this activity the pharmacy technician will be able to:
1. Describe the role that selected medications play and their effect on metabolic pathways.
2. Identify patients who, based on their drug regimen, should be referred to the pharmacist for nutritional supplement counseling.
3. Design a plan to develop a profitable nutritional niche by preventing drug-induced nutrient depletions.

INTRODUCTION
Pharmacists are the most highly trained health care professionals on pharmacodynamics, including drug mechanism of action and adverse effects. When you stop to consider all of the time the pharmacist spends taking classes in physiology, biochemistry, pharmacology, organic and inorganic chemistry, and other related sciences, it is a challenge to find any other conventionally-trained health care practitioner who can match the pharmacist’s professional training and background. They should be considered experts who can provide accurate information on nutritional supplements and their role in patient health care. The public has long recognized the value of this training in the pharmacist and regularly seeks out pharmacists for verification and validation of information found in the media or on the internet. The pharmacist holds a unique and valuable position in the multiple prescriber, multiple prescription health care environment that exists today. Daily, pharmacists accept the responsibility of detecting possible interactions and adverse effects that can occur with multiple prescribers and too many medications.

Pharmacists have long been the most accessible health care professional in the marketplace. In the regular course of their day, pharmacists routinely see patients who fit the criteria for groups identified as being at risk for nutritional deficiencies. Each day pharmacists service athletes who are undergoing intense training and competition, bariatric surgery patients with altered nutrient absorption, obese patients, patients with diabetes, individuals on weight reduction and weight management programs, and cancer patients. But perhaps the largest group of patients subject to nutrient depletions is the most overlooked; those patients who are at risk for drug-induced nutrient depletions. A deficiency is due to inadequate dietary intake. A depletion is a loss created by an outside influence such as a prescription medication. In other words, many patients are at risk of a nutrient depletion caused by drug therapy. This last patient group is the subject of this article. Some patients in the previously mentioned, specific patient groups can be hard to identify. However pharmacists who oversee drug administration and/or dispensing are perfectly situated to identify patients at risk for drug-induced nutrient depletion. It would only follow that a pharmacist involved in the process of dispensing medications that may ultimately
create drug-induced nutrient depletion should shoulder some responsibility for preventing those deficiencies.

Looking at this situation from the business side, pharmacies manage their prescription drug inventory to satisfy the needs of the patients that they see. Pharmacies should take care however, to maintain nutritional supplement inventory variety and quantities sufficient to address the nutritional depletions created by prescribed medications. A well-managed nutritional supplement department is good not only for patient health, but for the health of the pharmacy business. As profit margins continue to decrease on prescription medications, the margins on nutritional supplements continue to be healthy and can be a welcome source of revenue for a pharmacy. Research has demonstrated that the nutritional supplement market is a multi-billion dollar business. Studies have estimated that 70 percent of Americans are taking some type of nutritional supplement and are constantly seeking a source for reliable education on their supplements.

EDUCATION
The introduction described some of the areas of formal training that most pharmacists experience. However, undergraduate training in nutrition and the role of supplements in contemporary patient care is quite often overlooked. Pharmacists are routinely trained in drug/drug, drug/diet and drug/herb interactions in regard to the medications they dispense. But training to think critically about drug/metabolic interactions and the symptoms of nutrient depletion is inconsistent. Many health care professionals are more likely to add a drug to treat a symptom than they are to attribute symptoms to a nutrient depletion and recommend supplementation. The concept of looking for drug-induced nutrient depletions secondary to prescription medications is NOT regularly taught in either pharmacy or medical school. Given the pharmacist’s education, he or she is best suited to assimilate the information to go forward in this area.

In learning something new, often the first step is to unlearn something old. And that something old that we need to unlearn is the concept of the Recommended Daily Allowance (RDA), found on every Supplement Facts and Nutrition Facts label, and its value in contemporary nutrition. The RDA was established by the U.S. government in the 1930s to act as a guide in preventing nutritionally based diseases, such as rickets, pellagra, beriberi, and other nutritionally based diseases found in other parts of the world. By recommending that Americans consume the minimum allowance of various nutrients, it was believed that such problems could be prevented in the United States.

However, since the 1930s there have been several significant changes in the nutritional foundation of Americans that make the RDA of the 1930s archaic and incapable of addressing contemporary nutritional challenges. For the past 20 years health and nutrition experts have been frustrated by the growing prevalence of a high-fat, high-sugar, highly refined diet or, the “standard American diet,” often referred to as the “SAD diet.” Unfortunately nutrient wise, that is just what it has become. The unhealthy diet of many Americans may support life, but does not support or encourage health. The nutritional choices made by Americans today are void of healthful nutrients. Yet the abundance and convenience of such items as processed foods encourages their consumption, which leads to inflammatory processes in the body, promotes obesity and discourages health. Over the years since the 1930s, the nutritional value of even healthy food, particularly fresh fruits and vegetables, has deteriorated. Studies performed by the U.S. Department of Agriculture have charted an ever decreasing level of nutrients in the produce consumed in this country. The blame for much of this is attributed to the factory farming methods of agriculture today versus the farming methods of the 1930s and ‘40s.

Along with their nutrient deficient diet, Americans today are consuming more drugs and are exposed to more chemicals than ever before in our history. These drugs, dispensed in large part by pharmacists, along with other chemical and environmental exposure, result in noteworthy nutritional deficiencies with accompanying metabolic disruptions. It is well known that many of the diseases that plague us today, such as cancer, obesity, and Type 2 diabetes, are subject to a nutritional influence in regards to their development and outcome. We have all
seen images of starving children with nutrient-poor diets in third world countries. However, a large portion of the U.S. population, the 70 percent that are either overweight or clinically obese, should be considered nutrient-poor as well. Though good nutrition has a place in overall health, nutrient deficiency in the United States can’t be blamed solely on drug-induced nutrient depletion.

**NATURE AND SCOPE OF DRUG-INDUCED NUTRIENT DEPLETIONS**

“You cannot poison a crucial enzyme, block an important receptor, or interfere with a metabolic function for the long term and expect a good result”

—David Brownstein, MD, *Drugs that Don’t Work and Natural Therapies that Do*

The issue that we need to look at here is not whether alternative or complementary therapies are superior to prescription medications, but instead the way in which drugs work in the body and their effect on metabolic pathways. Most medications work by inserting themselves chemically into various metabolic pathways. One only has to review the mechanism of action of a medication to see terms like “inhibitor,” “modifier,” “agonist,” and other similar terms that would indicate a change in metabolic pathways created by the presence of a drug. When inserted into these pathways, drugs can affect nutrient absorption, synthesis, transport, storage, metabolism and excretion. That is the crux of Brownstein’s statement. What is the ultimate nutritional and metabolic outcome to the patient from the long-term usage of drugs in the body? Is it possible that drugs, when taken over time, have the potential to create problems equal to or greater than the disease state for which they were initially prescribed to treat?

Pharmacy and medicine are very endpoint and outcome oriented. “Have we lowered the cholesterol levels sufficiently?” “Have we provided symptom relief for the patient complaining of esophageal reflux issues?” Clinicians who fail to take into consideration the potential nutrient depletions which accompany long-term medication administration, ultimately undermine the patient’s health and well-being as well. Nutrients are critical to normal body function. The various vitamins, minerals and other micronutrients taken up daily in our diet, facilitate the thousands of metabolic processes that occur in the body. A review of the normal biochemistry of the body does not reveal a requirement for any of the drugs and other chemicals which we consume on a daily basis. It does, however, denote a need for enzymes, co-enzymes, and other nutrients essential for life as we know it. Additionally, drug-induced nutrient depletions can be multifactorial. We can reliably identify nutrient depletions specific to a particular drug. However, what happens in the case of the patient who is taking multiple drugs, all inserting themselves into various metabolic pathways and adversely affecting the overall ability for the patient to properly utilize nutrients? This is a definite consideration in the geriatric population who tend to have more extensive medication profiles along with decreased drug clearance functions. Finally, there is the insidious nature of problems that can arise in patients from extended nutrient depletion. These problems, brought about by drug-induced nutrient depletion, can arise several months after beginning a drug. When the problems arise, they may not be quickly connected to the introduction of a medication that occurred six months prior. Instead, they are viewed by the physician as a new complaint warranting the addition of yet another drug. For the pharmacist who is cognizant of nutrient depletions, it provides the opportunity to look back on prescriptions begun six months prior, and ideally sparing the patient from adding yet another drug to their profile.

The scope of drug-induced nutrient depletions directly correlates with the endless introduction of new products into the patient population. In 1999, when Ross Pelton and James Lavelle created “The Drug-Induced Nutrient Depletion Handbook,” their text was essentially a pocket sized reference, cross-referenced by nutrient depleted and depleting drug. In 2008 Stargrove, Treasure, and McKee’s text, “Herb, Nutrient, and Drug Interactions,” had grown to a full-sized text of 800-plus pages. Even as our knowledge of drug-induced nutrient depletions increases, our arsenal of drugs continues to grow and it will remain a challenge to the pharmacist to manage all of the necessary information in a practical fashion.
SELECTED, POPULAR MEDICATIONS AND THEIR EFFECT ON NUTRIENT DEPLETIONS

The products selected for this in-depth discussion represent just a few of the many drugs that have been shown to create drug-induced nutrient depletions. The selection was based upon drugs with which most pharmacists are familiar and currently dispense to a large number of patients, demonstrating the applicability of nutrient depletion counseling in any pharmacy practice.

Cholesterol Lowering Agents (HMG-CoA Reductase Inhibitors)

To hear the messaging in the media regarding cholesterol management, you would think that cholesterol serves no useful purpose in man and that the management of cholesterol and the reduction of cholesterol levels are absolutely essential for optimal health. This messaging is certainly heard by physicians as prescriptions for cholesterol lowering drugs account for $25–29 billion in sales each year and position the HMG-CoA reductase inhibitors (statin drugs) as the number one most prescribed prescription drug class in the United States. The HMG-CoA reductase inhibitors work by blocking HMG-CoA reductase, a rate-limiting enzyme in the production of cholesterol and an important electron carrier in cellular energy synthesis, Coenzyme Q10. While the medical community doesn’t typically worry about depleting cholesterol, it is necessary for health. A review of the role of cholesterol in the body (Table 1) demonstrates the purpose that cholesterol fulfills in the body.

Given the complex role that cholesterol plays in the body, the pursuit of lower cholesterol levels can result in problems in multiple body systems. As the precursor for the production of the adrenal stress hormones and the sex hormones, decreased cholesterol can result in a diminished capacity of the body to deal with chronic stress. Suppressed cholesterol will also inhibit the body’s ability to produce progesterone, estrogen, and testosterone in men and women. In individuals dealing with stressful situations, that stress can result in elevated cholesterol levels as the body responds to accommodate a greater need to synthesize those hormones. Vitamin D has received significant mention in the medical literature recently, as many individuals in the United States are already deficient in vitamin D. Drastically decreased cholesterol will inhibit vitamin D production. Cholesterol is also noted as being essential in the composition of the myelin sheath that covers the nerves. Finally, the brain requires cholesterol for competent cognitive function. A dramatic decrease in the level of cholesterol in the brain helps account for the brain fog, dementia, and depression listed in the drug monographs for these products.

However, as mentioned previously, inhibiting HMG CoA reductase inhibits the synthesis of coenzyme Q10 (CoQ10) which may lead to symptoms of deficiency. A review of the mevalonate pathway demonstrates that CoQ10 is depleted before cholesterol lowering even begins. In practice, this depletion in CoQ10 will be expressed as patient complaints of muscle pain and weakness, body aches and pains, brain fog, dementia, and potentially heart failure, as CoQ10 is essential for cardiac function. These depletion-based problems can be addressed by supplementing 100 mg of CoQ10 or 100 mg of ubiquinol, the active metabolite of CoQ10, for each medication known to deplete CoQ10 that a patient may be taking. If the pharmacist believes in the protective effects of statin drugs, then it would follow that a recommendation for the supplementation of CoQ10 100 mg would accompany any prescription for these products. Taking the pharmacist’s involvement one step further, patient discussion of complementary options for lowering cholesterol such diet, exercise, policosanol, berberine, and fish oil may be perceived as a valuable adjunct to help lower cholesterol levels without depleting CoQ10 and help minimize the dosage of statin necessary to get the desired clinical results.

Table 1. Selected Roles for Cholesterol in the Body

| 1. Cholesterol is necessary for mammalian cell membrane stability. |
| 2. Cholesterol is the precursor for the production of all adrenal stress hormones. |
| 3. Cholesterol is the precursor for the sex hormones. |
| 4. Cholesterol serves as a precursor to vitamin D. |
| 5. Cholesterol is necessary for dietary fat and mineral absorption. |
| 6. Cholesterol is essential for the myelin sheath that covers the nerves. |
| 7. Cholesterol is critical for cognitive function. |
H2 Antagonists and Proton Pump Inhibitors
Given the poor diet and high-stress lifestyle of most Americans, it is no wonder that the number of prescriptions for acid-lowering medications such as Proton Pump Inhibitors and H2 Antagonists are second only to statin drugs in the number of prescriptions filled each year. By blocking an enzyme in the gastric parietal cell, the proton pump that secretes stomach acid cannot secrete acid into the stomach. Without acid production, the pH of the stomach will rise abnormally, inhibiting effective protein digestion.

Looking at Table 2, we can see the critical role that stomach acid plays in digestion and the immune system. Once protein has left the mouth, the stomach is the last location to specifically break down protein for nutrient absorption in the digestive tract. Given the haste with which many individuals consume their meals, proper digestion of protein can present a real challenge. Digested protein is the primary source of vitamin B12, folic acid and the rest of the B vitamins. Protein needs to be thoroughly and properly digested to release these vitamins for absorption. Individuals who practice a vegetarian diet are often deficient in these vitamins due to lack of protein. Inadequate acid production can also account for compromised absorption of the minerals iron, zinc, copper and calcium. Of even greater importance than protein digestion and nutrient absorption, is the role the acidic pH of the stomach plays as a barrier to food borne infections. The results of reduced stomach acid can be seen in Table 3.

A complication also seen when addressing symptoms of perceived hyperacidity is the similarity of the symptoms of hyperacidity and hypoaclivity, having too little stomach acid. It is estimated that 46 percent of patients presenting with complaints attributed to hyperacidity are actually suffering from too little stomach acid. When recommending nutritional supplementation to compensate for nutrient depletions secondary to usage of PPIs or H2 antagonists, the pharmacist may attempt to determine whether too little acid or too much acid may be the true cause of complaints.

In the absence of a gastric ulcer this is done by consuming a teaspoonful of vinegar dissolved in a small amount of water just before eating. If the addition of the acid from the vinegar relieves the GERD (gastroesophageal reflux disease) symptoms, too little acid is the problem, as opposed to not enough acid. Suggestions for lifestyle and diet modification, along with recommendations for supplementation with betaine, glutamine or digestive enzymes to improve and enhance digestion and protein breakdown, may bring relief to patients. Lifestyle changes such as better chewing, not eating on the run, eating smaller meals, and not eating late in the evening can all impact the appearance of GERD symptoms and therefore use of PPIs and H2 antagonists. Such recommendations may prevent the long-term nutritional and digestive problems that can occur from extended usage of PPIs and H2 antagonists.

Estrogen Based Replacement Products
The nutritional deficiencies accompanying combined hormonal oral contraceptive (COC) usage have been noted since 1975. A number of small studies report that levels of folic acid, vitamin B6, and vitamin B12 are lower in women who take COCs than those who do not. The mechanism of the depletion is not clear and randomized, controlled clinical trials are needed to evaluate causation and clinical significance. Until such time that studies are available, women taking COCs, any type of estrogen supplementation or estrogen-progesterone hormone replacement should be monitored for signs and symptoms of deficiency.

<table>
<thead>
<tr>
<th>Table 2. The Role of Stomach Acid in Digestion</th>
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<tbody>
<tr>
<td>1. Stomach acid breaks down dietary protein.</td>
</tr>
<tr>
<td>2. Stomach acid enhances the availability and absorption of B vitamins.</td>
</tr>
<tr>
<td>3. Stomach acid helps reduce the trivalent ferric iron to ferrous iron for absorption.</td>
</tr>
<tr>
<td>4. Stomach acid protects the body from food borne infections.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3. Problems Resulting From Reduced Stomach Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Increase in gastric cancer and colon cancer</td>
</tr>
<tr>
<td>2. Vitamin and mineral deficiencies, especially B12</td>
</tr>
<tr>
<td>3. Increased incidence of allergic reactions due to the presence of undigested, intact protein in the lower G.I.</td>
</tr>
<tr>
<td>4. Bacterial overgrowth due to gastric pH change. Increase in H. pylori and C. difficile infections.</td>
</tr>
<tr>
<td>5. Increase in yeast and candida infections.</td>
</tr>
</tbody>
</table>
Long term B-vitamin depletion creates damage to blood vessels. Depletion of folic acid has been clearly shown in the literature to adversely affect cellular division and replication and cause neural tube defects. The health issues that are associated with long-term nutrient depletion secondary to estrogen administration are listed in Table 4. Once again, a valuable recommendation by the pharmacist would be the supplementation of folic acid, or better yet, the active form of folic acid, L-methylfolate and a complete B-vitamin complex for all women using estrogen replacement.

### Table 4. Symptoms Associated With Nutrient Depletion From Long-Term Estrogen or Oral Contraceptive Usage

- 1. Anemia, weakness, low energy
- 2. Increase in birth defects
- 3. Cervical dysplasia
- 4. Elevated homocysteine levels
- 5. Depression
- 6. Sleep disorders
- 7. Vascular disorders: stroke, blood clots, heart attack
- 8. Increased incidence of breast, uterine and colorectal cancer

**Antibiotic Therapy**

So far this discussion has lent itself to the nutrient depletions accompanying extended medication usage. Drugs such as statins and acid-lowering medications are all being reviewed for the adverse metabolic effects which accompany long term usage (six to 12 months). But one of the most significant metabolic disruptions that can occur is associated with the administration of antibiotics; a course of therapy may last for only five to 14 days, yet create a long-term depleted state.

The microbiome, more commonly known as the gut flora, is a synergistic balance of bacteria, yeast and other microbes that are essential for the maintenance of good health. Some of the essential roles played by the gut flora are:

- Digestion of food and absorption of essential nutrients
- Destruction of ingested toxins
- Production of short chain fatty acids that provide 5-10% of our daily energy supply
- Synthesis of vitamin K, niacin, vitamins B6, B12 and folic acid
- Maintenance of our immune system

It is estimated that more than 70 percent of our immune process is dependent upon the gut flora. Researchers are looking closely at the role that this gut flora plays in the development of cancer, irritable bowel disease, colitis, arthritis, and even obesity. As part of their function, antibiotics eliminate both pathogenic bacteria and good bacteria, resulting in an imbalance and disruption of the normal gut flora. The prevalence of vaginal candida infections in women following antibiotic administration is one example of how this imbalance can be expressed. Other disease entities that have been associated with disruptions in gut flora secondary to antibiotic usage are:

- Increase in fungal infections
- Increase in allergic asthma
- Increase in allergies
- Increase in eczema

Long term or repeated courses of antibiotics and their effect on gut flora can result in depletions in folic acid, inositol, and vitamins B1, B2, B3, and B12. To help offset these potential effects, pharmacists should be routinely recommending quality probiotics, particularly formulations which contain the yeast *Saccharomyces boulardii* when they are providing antibiotics to patients. And to help restore depleted gut flora quickly, fructooligosaccharides or FOS powder should be recommended as well to help accelerate gut flora restoration.

**ADDRESSING PRE-EXISTING NUTRITIONAL DEFICIENCIES**

One of the strongest arguments against the value of the Recommended Daily Allowance (RDA) discussed earlier in this article is the existence of established vitamin deficiencies in the U.S. population. Researchers have found that as much as 75 percent of the U.S. population is deficient in vitamin D, 60-70 percent of the population is deficient in magnesium, and 34 percent is deficient in zinc. Each of these nutrients has an important role in maintaining and protecting health. Vitamin D is referred to as a fat soluble vitamin, but actually performs in the body as a hormone. The active form of vitamin D is 1,25-dihydroxycholecalciferol and can be measured in the serum through routine lab testing. This allows
patients and physicians the ability to determine if an actual vitamin D deficiency exists. In our body, vitamin D aids in the absorption of calcium from the intestinal tract, helps the body assimilate phosphorous, stimulates bone mineralization, and helps the pancreas release insulin.

Magnesium is involved in more than 300 enzymes used in various metabolic pathways throughout the body. Most importantly, magnesium serves as a cofactor for the production of ATP, the body’s energy source. Magnesium plays a critical role in the body for sleep, heart function and rhythm, muscle strength and endurance, and nerve function, just to name a few. That is why loss or deficiency in magnesium can result in a wide range of symptoms. These symptoms of deficiency can include insomnia, heart arrhythmia, cardiovascular disease, fatigue, and complaints of muscle pain and spasm. Zinc is also widely used in the various enzymatic pathways in the body. One-hundred specific enzymatic reactions requiring zinc as a cofactor have been determined. Zinc is essential for taste and appetite, is critical for prostate health, promotes thyroid activity, and is essential in the utilization of insulin by the body. Just like magnesium, a deficiency in zinc results in a long listing of symptoms and complaints including hair loss, impaired wound healing, decreased sexual function, fatigue and immune deficiencies. Given the extensive number of metabolic pathways supported by vitamin D, magnesium, and zinc, functional medicine practitioners and clinical nutritionists routinely recommend supplementation with these three supplements to offset these pre-existing deficiencies found in the population. Table 5 lists these three nutrients and some of the common medications which deplete these nutrients in the body, further exacerbating pre-existing deficiencies.

**Table 5. Selected Drug-Induced Nutrient Depletions For Vitamin D, Magnesium and Zinc**

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Depleting Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin D</td>
<td>Antacids, Anticonvulsants, Bile Acid Sequestrants, H2 Blockers, PPIs</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Antihypertensives, Estrogen, Digoxin</td>
</tr>
<tr>
<td>Zinc</td>
<td>Antihypertensives, Estrogen, H2 Blockers, PPIs</td>
</tr>
</tbody>
</table>

**DRUG-INDUCED NUTRIENT DEPLETION: PROFITING FROM THE RESPONSIBILITY**

As was pointed out at the beginning of this article, pharmacists should be the most recognized and sought after experts in the distribution of accurate information concerning nutritional supplementation. To review, pharmacists:

1. Are the most highly trained health care professional in pharmaceutical information and should be able to offer the most valuable nutritional consultations.
2. Are recognized by the public as the expert on pharmaceutical and non-pharmaceutical medication interactions.
3. Are uniquely positioned in the health care dynamic to review poly-drug usage and evaluate for potential interactions.
4. Are the most accessible health care provider to patients.
5. Routinely see patient groups requiring specific nutritional consultation such as diabetics, the obese, bariatric surgery patients, athletes, and cancer patients.
6. The health care provider ultimately responsible for the dispensing of medications which can result in long term drug-induced nutrient depletions.

So with that being said, why doesn’t every pharmacist grasp the opportunity to address this responsibility? The answer to that question lies in two areas; education and investment.

**Education**

The public has increased its desire for more information in the areas of functional and integrative medicine. In response, the number of books, articles, and websites available to the public exploded. Pharmacists and physicians find themselves without enough time to read, much less critique, lay literature. Patients can find information based on poor, or proper, scientific studies that reinforce their personal beliefs or conclusions. However, there are competent texts and reference sources available which can provide the pharmacist with sound, scientific
nutritional information quickly. It is not necessary for a pharmacist to have a working knowledge of functional medicine or clinical nutrition to provide competent consultation to patients regarding nutrient deficiencies and drug-induced nutrient depletions. Learning the nutrient depletions created by a particular medication is no different than learning another indication or side effect for that medication. Nutrient information is simply information that is built upon the pharmaceutical knowledge base already possessed by the pharmacist.

Investment
Making recommendations for nutritional supplements to offset drug-induced nutrient depletions does require an investment in some nutritional inventory. For pharmacists with professional stores with little front end space, the idea of carrying sufficient inventory to offer any type of nutritional support may seem unrealistic. Likewise, pharmacists who already have stores with many feet of shelf space dedicated to supplements may resist paring down their product offerings to just the products that sell and make a good margin and bring in pharmaceutical grade dietary supplement lines. Since dietary supplements are not regulated as drugs, “pharmaceutical grade” does not mean FDA-approval; instead it means that the manufacturer has implemented a program of independent analysis of product purity and bioavailability.

The key to inventory management relies on the pharmacist’s recommendation of a specific product for a specific nutrient depletion; not on stocking every nutritional product that a patient may be seeking. Looking at the nutritional supplement inventories of physicians who practice functional medicine and recommend nutritional supplements to their patients, a very successful nutrient niche can be developed by allocating a three to four foot section of shelf space in an office setting. The goal is to not have the exhaustive vitamin inventory present at a vitamin store, health foods store, or large chain store. The goal is to have the specific inventory curated by a pharmacist that can be recommended by the pharmacist to patients based upon the prescriptions they take. With ever decreasing margins seen in conventional medication dispensing, the addition of a companion sale for nutritional support can be a welcome addition to the bottom line of the pharmacy and a valuable measure against future health complication to the patient.

PLAN FOR PROFITABILITY
Pharmacists who fail to embrace the responsibility of addressing drug induced nutrient depletions are failing their patients and failing to capture a potentially profitable professional niche. To that end, I would offer the following plan for developing a nutritional support service based on drug-induced nutrient depletions:

1. Survey current prescription records and identify those products generating greatest number of sales or sales volume.
2. Determine the associated drug-induced nutrient depletions associated with those products. Sources for this information are:
   • The University of Maryland Medical Center Complementary and Alternative Medicine Guide (http://umm.edu/health/medical/altmed)
   • “Drug-Induced Nutrient Depletion Handbook” (Pelton and Lavalle, 2001)
   • “Herb, Nutrient and Drug Interactions” (Stargrove, Treasure, McKee, 2007)
   • Natural Standard Database (www.NaturalStandard.com, subscription web database)
3. Incorporate recommended nutritional supplementation into prescription processing software.
4. Create patient messaging that explains why pharmacist is recommending supplementation.
5. Attach supplement to the prescription at prescription pick up point.
6. Create additional patient centered messaging that discusses drug-induced nutrient depletion and the benefits of nutritional supplementation for other medications the patient may be taking.

John Preckshot, RPh, CCN, is PCCA Director of Wellness Works. The conflict of interest was resolved by peer review of the content of this monograph.
Drug-Induced Nutrient Depletion: The Pharmacist’s Responsibility
Dec. 2, 2013 (expires Dec. 2, 2016) • Activity Type: Knowledge-based

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A score of 70 percent is required to successfully complete the CE quiz. If a passing score is not achieved, one free reexamination is permitted.

CONTINUING EDUCATION QUIZ
Select the correct answer.

1. Which is NOT a reason why pharmacists should be the experts in nutritional supplementation?
   a. Pharmacists have extensive training in the pharmaceutical sciences.
   b. Pharmacists have access to patient prescription records.
   c. Pharmacists are not trained to identify nutrient deficiency.
   d. Pharmacists are highly accessible to patients.

2. Which of these groups are known to develop nutritional deficiencies?
   a. Geriatric patients
   b. Bariatric surgery patients
   c. Cancer patients
   d. Patients on weight loss programs
   e. All of the above

3. Which is not a nutrient deficiency disease?
   a. Alzheimer’s
   b. Beriberi
   c. Scurvy
   d. Pellagra
   e. Rickets

4. Which statements are false?
   a. The RDA is the upper limit daily dose of vitamins
   b. The RDA for dietary fats is 5–10 percent of daily calories.
   c. Whole fruits and vegetables contain more nutrients today than ever before.
   d. All statements are true.
   e. All statements are false.

5. When inserted into metabolic pathways, drugs can affect nutrient______ (fill in the blank)
   a. Absorption
   b. Synthesis
   c. Metabolism
   d. Excretion
   e. All of the above

6. When examining drug-induced nutrient depletion which of the following is true?
   a. Complementary or alternative therapies are superior to pharmaceutical options.
   b. Drug-induced nutrient depletions normally express themselves within two weeks of starting a medication.
   c. Drug-induced nutrient depletions can create long term health issues if not addressed.
   d. Prescription drugs approved after 2011 have submitted findings from clinical trials showing no evidence of drug-induced nutrient depletions.

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7. Which is not a function of cholesterol in the body?
   a. Cholesterol serves as a precursor for the production of the sex hormones.
   b. Cholesterol serves as a precursor for vitamin D.
   c. Cholesterol is essential for the myelin sheath that covers the nerves.
   d. All of the statements are true.

8. A fictional HMG CoA Reductase inhibitor drug was approved in 2013. What might a pharmacy do to anticipate prescriptions for this drug?
   a. Pre-order inventory and wait for clinical studies to see if it affects Coenzyme Q10 synthesis.
   b. Draft a fax communications for local cardiologists reminding them of the importance to supplement folic acid when taking “statin” drugs.
   c. Draft a bag stuffer for all “statin” drug patients with information about Coenzyme Q10 depletion.
   d. No special action is required; drugs approved after 2011 do not deplete nutrients.

9. Which is a role for stomach acid?
   a. Breaks down dietary protein
   b. Enhances the availability and absorption of B vitamins
   c. Reduces the trivalent ferric iron to ferrous iron for absorption
   d. Protects the body from food borne infections
   e. All are functions of stomach acid.

10. J.P. is a 45-year old male patient who has been using cycles of a “cleanse diet” to detoxify and lose weight. He presents to the pharmacy today looking for a supplement to give him more energy. The pharmacist advises J.P. that his weight loss plan may not be providing him with essential nutrients. Which of the following should be ruled out as a possible cause of J.P.’s low energy?
    a. Anemia due to Vitamin B12 deficiency
    b. Anemia due to iron deficiency
    c. Anemia due to washout of gut flora
    d. A and B Only

11. Nutrient supplementation is recommended for which of the following?
    a. Oral contraceptives
    b. Manufactured estrogen replacement.
    c. Bio-identical hormone replacement
    d. All of the above.
    e. None of the above.

12. The appropriate primary nutrient supplementation for patients on estrogens is?
    a. Calcium and magnesium
    b. L-methylfolate and B vitamin complex
    c. Vitamins E and A
    d. A statin drug and a PPI
    e. Probiotics and FOS powder

13. Which of the following may occur secondary to antibiotic usage?
    a. Vaginal yeast infections
    b. Flare of allergic asthma
    c. Flare of eczema
    d. All of the above
    e. A and b only

14. Which is the true statement regarding antibiotic usage?
    a. Repeated short courses of antibiotics will not deplete gut flora.
    b. Antibiotics are non-specific and eliminate both pathogenic and non-pathogenic bacteria.
    c. Taking antibiotics along with yogurt will not disrupt gut flora.
    d. Antibiotics alter gut flora, but do not create nutrient depletions.
    e. Ten percent of our immune function is in the gut.
15. More than 50 percent of individuals in the United States demonstrate a deficiency in which of these supplements?
   a. Vitamin D
   b. Magnesium
   c. Zinc
   d. All of the above
   e. A and b only

16. Which of these nutrient levels can be routinely measured in a standard blood test?
   a. Coenzyme Q-10
   b. Vitamin D
   c. Vitamin A
   d. None of the above
   e. All of the above

17. A patient presents to you with a complaint of altered taste sensation. What would be a reasonable recommendation for a supplement to use?
   a. Vitamin D
   b. Magnesium
   c. Zinc
   d. Coenzyme Q-10
   e. B complex

18. Which of the following is the gold standard test for detecting a nutrient depletion?
   a. Expensive testing is not needed, recommend 325 mg ferrous sulfate once daily and assess labs in four weeks.
   b. Expensive testing is not needed, recommend a complete daily multivitamin.
   c. DNA analysis to reveal genetic predisposition to nutrient deficiency
   d. There is no single test to detect nutrient depletions due to involvement in complex metabolic pathways.

19. R.S. is a 52-year-old female patient who regularly fills her omeprazole prescription after being diagnosed with Barrett’s Esophagus. What recommendations does her pharmacist make when her bone mineral density screening reports a T-score of -1.1?
   a. Supplement dietary intake of magnesium, calcium and vitamin D to compensate for decreased absorption due to stomach acid changes
   b. Supplement with Ubiquinol to prevent cognitive changes that would lead to memory loss and poor adherence
   c. Supplement dietary intake of vitamin A to compensate for decreased calcium absorption
   d. No supplementation is recommended for R.S.

20. Pharmacists have an advantage in recommending nutritional support for their patients taking prescription medications because:
   a. They already possess their prescription records and profiles
   b. They can program their computer software to inform the pharmacist when the patient is getting a prescription with a noted nutrient depletion problem
   c. Pharmacists have the public’s trust and respect.
   d. A, b and c
   e. A and C
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Continued from page 12 ➔ was not harmed. This case should serve as a strong reminder to keep all medications secured and out of the reach and sight of children, even if the caregiver is in the same area as the child. It is also important to teach children about medication safety, to tell them what medicine is, and why their parent or caregiver must be the one to give it to them. More than 60,000 young children end up in emergency departments every year because they got into medicines while their parent or caregiver was not looking. For more information and strategies to protect children from unintentional medication overdoses, visit the Up and Away and Out of Sight educational program at: www.upandaway.org.

HIGH-ALERT MEDICATIONS
CONSUMER LEAFLETS
Between 2008 and 2012, the Institute for Safe Medication Practices (ISMP) was awarded a grant from the Agency for Healthcare Research and Quality to conduct a study in community pharmacies regarding the impact of counseling consumers who pick up prescriptions for certain high-alert medications. The medications involved in this study include:

• warfarin
• enoxaparin
• fentaNYL patches
• methotrexate (oral)
• HYDROcodone with acetaminophen
• oxyCODONE with acetaminophen
• insulin analogs (lispro, aspart, glargine, glulisine, detemir)

You can access one of the resources created during this study: consumer leaflets that include patient education checklists. The leaflets offer important safety tips for taking each medication safely. The leaflets are FREELY available on the ISMP website (www.ismp.org/AHRQ/default.asp) and can be reproduced for free distribution to consumers.

This article is from the Institute for Safe Medication Practices. ISMP can be reached at 215-947-7797 or ismpinfo@ismp.org.
Past Prologue for 2014 State Legislative Sessions?

by Michael F. Conlan

With most state legislatures looking ahead to new sessions next month, now is a good time to review NCPA’s recent accomplishments around the country. In the past couple of years, NCPA has ramped up its focus on the states. We are concentrating our energy in supporting the work of state pharmacy associations and organizations to help community pharmacies. This year community pharmacy went head-to-head with pharmacy benefit managers in a number of states and won more than its share of those battles. Six states, for example, now have transparency laws requiring maximum allowable cost generic drug price updates to be done in a timely manner. Getting more states to enact these bills is more important than ever as we work on solutions to the rash of sudden and enormous generic drug price increases.

Four states now have anti-mandatory mail order laws on the books. The most recent was in Hawaii where patients can fill their prescriptions at one of the Aloha State’s 95 independent pharmacies instead of being required to have their medicines shipped across the Pacific from mainland mail order plants.

In addition, the same day Gov. Neil Abercrombie (D) enacted the anti-mandatory mail order bill, he also signed into law a bill that restricts the ability of PBMs to use patients’ private medical information as a marketing tool in order to try and steer them into “preferred pharmacy” plans affiliated with the PBM. Earlier this year NCPA analyzed 2013 data on the Medicare Plan Finder website to compare the full costs of four commonly used medications between preferred and non-preferred pharmacies. That analysis found that most of the time the full cost was more expensive at preferred pharmacies than at non-preferred pharmacies. An analysis this summer by the Centers for Medicare & Medicaid Services (on our website) validated the questions about preferred pharmacy drug plans raised by NCPA, Medicare officials, 19 senators, 31 representatives, and MedPAC, the independent Medicare Payment Advisory Commission.

Another recent state victory occurred in Oregon where Gov. John Kitzhaber (D) signed a groundbreaking, three-part reform legislation that applies reasonable standards to how PBMs audit community pharmacies, provides increased transparency into generic prescription drug MAC reimbursement, and ensures that PBM administrators of prescription drug claims are registered with the state’s insurance division.

This legislation’s enactment came after a yearlong negotiation process. Members of a Pharmacy Working Group, which consisted of Oregon pharmacists, representatives of the Oregon Pharmacy Association, the National Association of Chain Drug Stores, NCPA, the Oregon Pharmacy Coalition, state legislators, and representatives of the PBM community, collaborated on these issues, resulting in the enacted law.

With Oregon’s provisions, 29 states now require fair and uniform pharmacy audits by PBMs. Additionally, 15 states have PBM registration, licensure, or reporting requirements.

Michael F. Conlan is editor of America’s Pharmacist.
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