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LIST ACCOUNT EXECUTIVE
Tamara Phillips
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(800) 200-5400 or (860) 225-4569 ext. 2742
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mcannon@advanstar.com

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Joy Puzzo
(440) 319-9570
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DIRECTOR
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(440) 319-2559
cshappell@advanstar.com

MANAGER
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jmartin@advanstar.com

CIRCULATION
24950 COUNTRY CLUB BLVD., SUITE 200
NORTH OLMSTED, OHIO 44070
MAIN NUMBER: (440) 243-8100
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COVER STORY

Beers Criteria Update

This unique guide to “Potentially Inappropriate Medication Use in Older Adults” is intended for use in all care settings and by all healthcare professionals. The latest revision focuses on new drugs, dosages, and evidence. PAGE 22

PRESCRIBED READING

8 MTM cuts hospital readmissions
Those high rates hit everyone where it hurts. Here’s a practical way to bring those numbers down.

17 PBMs strike back at copay discounts
Coupons and cards draw fire from CVS Caremark and ESI.

39 Controlled substances: e-Rx update
Vendors gear up to comply with DEA's interim final rule.

SPECIAL SECTION: GENERICS

45 The floodgates open
As blockbuster drugs go off patent, manufacturers scramble while pharmacists take the dramatic market shifts in stride.

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CONTINUING EDUCATION

Enhancing immunization rates

As advocates of public health through immunization, pharmacists can build public awareness, identify patient needs, and provide vaccination services. PAGE 28

COUNTER POINTS
10 LETTERS
Mail order has its say

11 STUDENT CORNER
DXM should be behind the counter

12 IN MY VIEW
Pharmacy’s evolving options

14 VIEW FROM THE ZOO
Deja vu all over again

48 JP AT LARGE
Natural doesn’t always equal harmless

ISSUES & TRENDS
15 UPFRONT
A nationwide network launches

CHAINS & BUSINESS
18 OIG REPORT
Independent pharmacies more likely to engage in fraud

HEALTH SYSTEMS
19 DRUG SHORTAGE
Ongoing crisis highlights importance of teamwork

20 ENVIRONMENTAL PATHOGENS
Better patient-room cleaning reduces HAIs

CLINICAL
27 ANTIICOAGULATION
Fondaparinux safe in renal impairment

38 NEW DRUG REVIEW
Pancrelipase DR caps approved

PRODUCT UPDATES
40 FIRST AID
New items for the summer first-aid kit

43 NEW PRODUCTS
FDA approves Belviq for chronic weight management

WEB EXCLUSIVES
Ranibizumab for DME
http://drugtopics.com/ranibiz

Online counterfeit drug supply
http://drugtopics.com/fake

High-dose vitamin D for elderly
http://drugtopics.com/vitd

DT BLOG
Where to from here?
In this month’s DT Blog post, contributor Stan Illich expands on his In My View column exploring the future of pharmacy. Read more at www.DrugTopics.com.

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MTM cuts hospital readmissions

Each day there are many discussions across the country about our healthcare system. These conversations occur across many settings, from hospitals and financial institutions to our very own dinner tables. While opinions vary significantly on a wide array of topics, there is one concern that most will agree is a significant priority in healthcare: hospital readmissions.

High hospital readmission rates have historically been an indicator of poor quality care. They are disruptive to caregivers and providers as well as to patients. Readmissions cost the healthcare system billions each year and put patients at risk for hospital-acquired infections and complications.

Studies, notably by Dr. Stephen Jencks, have shown this to be a pervasive problem, resulting in a considerable cost to fee-for-service (FFS) Medicare. Jencks estimated that readmissions within 30 days of discharge cost Medicare more than $17 billion annually. The problem is not limited to Medicare patients alone. Adult Medicaid patients are readmitted about twice as frequently as privately insured patients, regardless of the readmission period.

A range of causes

Healthcare practitioners and researchers indicate that high readmission rates for patients with chronic diseases and others may be due to various factors that fall under a range of causes, such as:

- Inadequate relay of information by hospital discharge planners to patients, caregivers, and post-acute care providers
- Poor patient adherence with care instructions
- Inadequate follow-up care by post-acute and long-term providers
- Variation in hospital bed supply
- Insufficient reliance on caregivers
- Deterioration of a patient’s clinical condition

The MTM toolkit

Medication Therapy Management (MTM) is one way pharmacists can help combat this ongoing concern. MTM includes analytical, consultative, educational, and monitoring services as well as numerous other tools and strategies that can be used to diminish readmission rates. MTM will increase patient adherence and increase understanding of therapy as well as control costs, while preventing drug interactions, duplications, and complications.

MTM enhances a patient’s understanding of appropriate drug use, which increases detection of adverse events. It targets vulnerable points of care, such as chronic disease states and complex or cognitively impaired patients, as well as transition points of care, while allowing pharmacists to intervene for medication-related problems, and enables them to refer patients to other practitioners (PCP, NP, LICSW) if necessary.

There are many disease states, such as CHF, COPD, and diabetes, for which MTM can prevent hospitalizations. This model empowers patients to take on a more active role in care management. Care becomes not only collaborative but also patient-centered. Patients walk away with a better understanding of their conditions and how to manage them.

Without MTM therapy, the impact on patient care and readmissions is extensive. The quality of patient care and outcomes would decrease, while medication-related problems, cost, and nonadherence would rise, worsening difficulties we face today.

Readmissions, while not all avoidable, are often preventable. To assess your practice’s aptitude in readmission management, you can use the following questions as a guide.

Readmission management checklist

- Does your facility have mechanisms in place to see patients within 5-7 days post-discharge? If you don’t have access to a discharge summary, have you contacted the inpatient provider?
- Have you established a mechanism for post-discharge medication reconciliation with PCP or pharmacist? Have patients been asked to bring in all medications for thorough evaluation?
- Do you currently have patient teach-back tools, educational aids, or other patient-centered strategies available?
- Do you address adherence at every consultation as well as in a follow-up program for highest-risk patients who miss appointments or refills?
- Do you create a patient-centered action plan with SMART goals?

Pharmacists have not only a dynamic and diverse knowledge base but also effective tools and strategies. They can educate, encourage, and empower patients through MTM therapy and other techniques, which in turn will lead to decreased overall hospitalizations and readmissions.

Derek McFerran is a clinical pharmacist with Tufts Health Plan in Watertown, Mass.
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In defense of mail order
Jim Polucha’s letter in the June issue of Drug Topics [“Not the last word on mail-order waste”] is just another example of someone trying to stereotype all mail-order pharmacies. Obviously he doesn’t know about the mail-order pharmacy I work for.

We do not automatically send out prescriptions when they can be refilled. We always wait for the patient to call, e-mail, or mail a refill request. We realize how expensive medications are, and if a patient’s copay has gone up excessively, we always call the patient to get approval on a copay before we send out a medication.

We also have a very good turnaround time, as we are a small mail-order company, primarily serving Wyoming customers. Our patients normally receive their medications within 2 to 5 days.

If we receive a prescription that needs to be clarified due to a change in medication, dosage, directions, etc., we always call the prescriber.

We also verify with patients any changes that can be expected, and we notify them of possible drug interactions or side effects.

It sounds as if Mr. Polucha should try to work with his fellow pharmacists (community and mail-order alike) in trying to solve problems, instead of pointing his finger at someone else without knowing all the facts.

He should not try to pigeonhole all mail-order pharmacies into one category to suit his purposes.

Sarah Stalker, RPh
CASPER, WYO.

Missed one
I have worked about half the time Paul Bergeron has in his 52 years, mostly in the independent setting. His list of terrible pharmacy decisions (Letters, “The wisdom of hindsight,” May 2012) was right on target, but he did omit the biggest detriment ever to the professionalism of pharmacy: the $4.00 prescription!

Larry Heiling, RPh
CONTINENTAL, OHIO
Counter Points

DXM and the threat to public health

On my public health rotation as a third-year pharmacy student, I was assigned to investigate dextromethorphan (DXM) abuse in minors, with the goal of raising awareness of this problem in the community. To my surprise, DXM abuse turned out to be a larger problem than I had anticipated. There is an unfortunate public perception, especially in teenagers, that since DXM is an over-the-counter medication, it is not dangerous. It doesn’t have the stigma of illicit drugs such as cocaine, methamphetamines, or heroin.

DXM is known by its street names: Triple-C, Candy, Dex, DM, Drex, Red Devils, Robo, Rojo, Skittles, Tussin, Velvet, and Vitamin D. Those who use the cough syrup to get high are sometimes called “syrup heads,” and DXM abuse is often called “dexing,” “robotripping,” or “robodosing.

Minors and most of the public do not understand that DXM, a cough suppressant, is also a central nervous system depressant. Ingesting large quantities can lead to irregular heartbeats, blackouts, seizure, brain damage, and even death. Minors who ingest combination drugs for recreational purposes — for example, dextromethorphan and acetaminophen — risk developing other complications, such as liver damage, in addition to the effects caused by DXM.

Growing problems

In response to the prevalence of DXM abuse, California prohibits the selling of nonprescription drugs containing DXM to those under the age of 18. Pharmacies are now required to check identifications at point of sale. However, many pharmacies do not always check identifications, and stocking DXM in the pharmacy’s cough and cold aisle makes it very accessible and easy for shoplifting. Pharmacies need to take this issue more seriously and consider putting DXM products behind the counter, especially in communities where DXM is being abused.

Mounting numbers

A national survey of 45,000 teenagers conducted in 2010 by the University of Michigan’s Institute of Social Research indicated that 3.2% of 8th graders, 5.1% of 10th graders, and 6.6% of 12th graders claimed that they had abused DXM during the previous year.

According to WebMD and the Consumer Healthcare Products Association, 1 in 10 teenagers say they’ve used DXM to get high; such a claim would make DXM more popular than LSD, cocaine, ecstasy, or methamphetamine.

In California, the Poison Control System reported that the subject of DXM abuse has been the most common telephone consultation provided to those between the ages of 6 and 17 since 2003.

Educators and resources

The Cardinal Health Foundation has partnered with APHA and APHA-ASA, setting goals to increase awareness among pharmacists and student pharmacists about the opportunity to serve as educators and health information resources for the prevention of medication abuse. Their goals include encouraging student pharmacists to implement prescription medication abuse prevention programming after graduation and promote the pharmacy and its valuable role in the community and in the healthcare delivery system.

I currently show parent groups at the schools a PowerPoint presentation I developed to educate families and students about the harm that DXM overdose can cause. I’d be more than happy to share this presentation with anyone interested in a project to educate middle and high school students as well as their parents on this important issue. [To receive more information, e-mail Clipper at the address provided below.]

Additional resources include:
- The Ohio State University College of Pharmacy: http://www.pharmacy.osu.edu/outreach/generation-rx/
- University of Utah School on Alcoholism and Other Drug Dependencies: http://medicine.utah.edu/us/OD

Clipper Young is a PharmD candidate, Touro University–California, Class of 2013. He welcomes e-mails at clipper.young@tu.edu.
IN MY VIEW Stan Illich, RPh, MHA

Maybe in your lifetime ...

... We should all be doctors

It appears that the efforts of academia and pharmacy leadership to move pharmacists to direct patient care are beginning to succeed. Pharmacy as we know it may eventually fade into obscurity.

Some will say that is exactly what we should be trying to accomplish. Our leaders in all areas of pharmacy seem to be absolutely and totally focused in this direction. This is a laudable goal; however, pursuing it to the exclusion of all other solutions will certainly have unintended consequences.

Then who would be the pharmacists?

I personally advocate that some pharmacists become specialists and function totally as providers, much as do physician assistants and/or nurse practitioners. This is a critical step in the evolution of pharmacy practice. But if we all become providers, what will become of the dispensing function?

Believe it or not, there is a clinical element to dispensing. Who will catch the errors made by providers, the comorbidities not considered, the drug interactions overlooked, the issues generated by the patient using multiple providers and multiple pharmacies? Who will consult with the provider who has written the prescription?

And what about the patient? Who will work with the patient on all aspects of the drug therapy? Will it be technicians? Or will those of us who do not have direct patient contact be relegated to technician status?

Will pharmacies need pharmacists? Chains and grocery stores would find this question very attractive.

Reality gap

Most pharmacists are still referred to by the intentionally negative title of “dispensing pharmacists.” This situation exists because pharmacists have always operated from a position that is weak.

Our practices are owned by others who do not share our professional goals. We have gone from being a group of professionals operating in a business atmosphere to drudges toiling in a never-ending, pressure-filled sweat shop. While we have patient-centered care foremost in our minds, in most cases the patient never gets to speak with the pharmacist. The laws that were put in place to ensure patient consultation with a pharmacist are useless. The result is demeaning and professionally nonexistent, and leaves many of us with an empty, helpless feeling.

Time really may be running out

The evolution of pharmacists to pure providers of direct patient care seems logical and even desirable; however, if this is the only path to resolution of our problems with professionalism, most of us will have to find other employment.

Efforts to enable “dispensing pharmacists” to perform clinical functions have been pursued for years with virtually no success. There must be a way to tap the knowledge, experience, and professional expertise of the 85% or so pharmacists who are not exclusive providers of direct patient care. There is no easy way to go from what we have to where academia and our leaders want to go. There must be an interim solution. If we don’t find it, the void will be filled by another profession.

An evolution to the kind of pharmacy we envision will take an extreme out-of-the-box solution, backed by all of pharmacy, to include those who are interested mostly in money and those who are interested in direct patient care and those who believe that a “dispensing pharmacist” can be “clinical.”

Possible directions

Some solutions we might consider:

• Lobby state legislatures to require pharmacists to own 52% of the pharmacy or stock therein, as in North Dakota.

• Change the pharmacy model in the chain and supermarket pharmacies to one that makes the profit they desire but allows the pharmacist to talk to every patient.

• Move to a patient-centered medical home model.

• Include pharmacists in physicians’ medical practices.

My pharmacy career is nearly at an end, and the only thing on my bucket list is a transition for the profession of pharmacy that works for all of pharmacy.

Are we up to the challenge?

Stan Illich practices at Peak Vista Community Health Centers in Colorado Springs, Colorado. You can e-mail him at stanillich@comcast.net. He expands on the “possible directions” suggested above in this month’s DT Blog, post featured at www.DrugTopics.com.
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Let’s do the time warp again

This may sound a little weird to you, but last month I spent an afternoon pondering whether my closet had become the sort of time-travel apparatus implied by Einstein’s theory of relativity. Actually, that probably sounds a lot weird, and I should probably explain before you turn the page.

Last month I was able to collect my reward for nine months of pharmacy action: my first paid vacation of the year. I decided to make clutter clearing the main goal of my time off and dove into a collection of boxes at the back of my closet to see what could be thrown away, sold off, recycled, or otherwise shown the exit from my life. A copy of a pharmacy trade magazine caught my eye and I took a little break from my cleaning to browse through the articles.

Deja vu all over again

“The chain drug industry continues to break new ground in its nationwide campaign to deliver a broader spectrum of reimbursed healthcare services to patients, managed care payers and integrated health networks,” the lead article said.

I put that issue down, grabbed another, and saw this: “There’s a great opportunity to work across the whole spectrum of the healthcare channel … We can cooperate with other healthcare providers and academic institutions to support research to evaluate the impact of patient care initiatives.”

This is when I became concerned. Because one of those articles was written in 1997, the other exactly one month ago. Can you tell which is which?

Let’s try another: “An integrated wellness approach to diabetes care can help patients not only improve their condition, but also lower their prescription costs” vs. “New legislation authorizing payment to pharmacists for diabetes care services has sailed through the state senate.”

Again, one of those quotes is 15 years older than the other. Any clue which came first?

The payment for services legislation. Are you being paid for diabetes care services? Didn’t think so.

Einstein’s theory of relativity predicted that time travel is indeed possible. Long story short, he concluded that if you could manage to move faster than the speed of light, your perception of time would change. That a month in your fast-moving rocket ship might seem like 15 years to those moving slower than light.

I remembered this as I continued to read and slowly began to suspect my closet had become a time portal.

“We are going to move away from the old practice of pharmacy, which was primarily transactional, to more of a personal relationship … This is a completely new pharmacy, health, and wellness experience with a focus on health outcomes.”

And this, about an organization that had “taken the wraps off its long-awaited ‘Pharmacy of the Future,’ a radically redesigned pharmacy that unites new concepts … The new format affirms in dramatic fashion the company’s intention to evolve its pharmacy practice beyond simple drug dispensing into the realm of integrated patient care and disease management.”

One of those quotes is 14 years old. I’m not telling you which. Either these magazines have indeed mastered time travel, being published last month while bearing dates from the ’90s, or, despite almost a generation of promises heralding a “pharmacy of the future,” from the perspective of the retail pharmacist, very little has changed.

There’s always next year

Sadly, I realized eventually that it wasn’t the time travel.

I wonder whether the “pharmacy of the future” manager who said in 1998, “We’re doing this for one reason, to help us free up time so we can spend more with the patients,” is actually spending more time with patients in 2012?

I’d be confident in betting the answer is an emphatic “no.”

The “pharmacy of the future” has turned out to be about more prescriptions, fewer resources, metrics that measure not time with patients but prescriptions out the door, and flu shot quotas.

The most dramatic change in the profession has not been the elimination of “count, pour, lick, and stick,” it has been the addition of one more stick — that of an arm or two between an ever-increasing number of prescriptions. I don’t remember reading anything about that in 1997.

Of course there’s always next year, or the year after that. I’ll put this magazine on a closet shelf and report back to you next time I feel like a little decluttering. Things will surely be better by 2027, right?

David Stanley is a practicing community pharmacist in California. He can be reached at drugmonkeyrph@gmail.com.
Drug Topics’ CPE accreditor begins 3-year AACP service

During the Annual Meeting of the American Association of Colleges of Pharmacy (AACP) in Kissimmee, Fla., which took place in mid-July, Jill Fitzgerald, PharmD, who is Drug Topics’ CPE accreditor, was sworn in as chair-elect to the AACP Continuing Professional Education Section.

Fitzgerald is director of Pharmacy Professional Development and assistant clinical professor at the University of Connecticut School of Pharmacy, in Storrs, Conn.

Now beginning her 3-year term, Fitzgerald is responsible for the development of programming for next year’s annual meeting as it relates to the Continuing Professional Education section.

In 2013, Fitzgerald will assume the role of chair, working to implement the organization’s strategic goals toward the advancement and practice of Pharmacy Continuing Professional Development. Then, during her final year, she will continue in the leadership of the Section as immediate past-chair.

Fitzgerald and her office serve in the role of accredited provider of continuing pharmacy education activities for Drug Topics magazine.

Together, the University of Connecticut School of Pharmacy and Drug Topics have joined forces to offer a new Continuing Pharmacy Education opportunity, providing up to 23 CPE credits of knowledge-, application-, and practice-based activities, with the new “Medication Therapy Management CPE Series” that commences in September 2012.

NEW PHARMACY NETWORK
RxAlly aims to fully integrate pharmacy into healthcare system

What do Walgreens, Kerr Drug, Kinney Drugs, USA Drug, and Rochester Drug Cooperative have in common? They are all members of RxAlly, a nationwide network of pharmacies with a desire to improve healthcare outcomes and lower costs, as well as to play an enhanced role within healthcare, according to RxAlly’s leader, Bruce T. Roberts, RPh, in an interview with Drug Topics.

In February 2012, RxAlly launched its Performance Network of more than 20,000 pharmacies with a mission to generate measurable improvements in patient health outcomes while reducing healthcare costs. It is well on its way to launching an integrated platform to accomplish this goal — connecting all these pharmacies’ data and aggregating it in a systematic way to address the challenges of lack of adherence.

“The only way to have pharmacy seen as a valuable player in healthcare is to have a large enough network, so that you can deliver a solution to the entire country,” said Roberts, CEO of RxAlly and former executive vice president of the National Community Pharmacists Association (NCPA). Even Walgreens, the largest pharmacy chain in the world with 8,000 stores, recognized the need to be part of a larger network to play an enhanced role in healthcare, he continued.

“One of the challenges for pharmacies, especially on the independent retail chain side, is that we don’t have this aggregated data or this interoperable link to the rest of healthcare,” Roberts said. “We [at RxAlly] are working to create the ability for pharmacy to link into the health information changes, ultimately link into the accountable care organizations.”

Reimbursement continues to be a major challenge for pharmacies. In fact, the pharmacy model that is solely focused on the commodity itself is a very challenging business model in terms of survival in the current marketplace, Roberts noted.

“Our aim at RxAlly is to form a network of like-minded pharmacies that are focused on ensuring that prescription medicines are used correctly and with the technology in place to really clearly demonstrate the value of pharmacy,” said Roberts.

Since its launch, RxAlly has added another 20 groups from regional chains and groups representing independents. For more information, go to www.rxally.com.

— Julia Talsma, Content Channel Director
Kent Hospital in Warwick, R.I., is stepping up its staff’s awareness of safe injection practices after the Centers for Disease Control and Prevention reported 40 outbreaks of infectious disease caused by unsafe injection practices. “These lapses in basic infection control include reusing needles and syringes from patient to patient or misusing single-dose and multi-dose vials,” wrote Peter Graves, MD, chairman of the Department of Emergency Medicine at Kent Hospital, in a guest blog at the CDC’s website.

The CDC’s Safe Injection Practices Coalition also reports that more than 130,000 patients have been notified that they might be at risk for blood-borne disease, resulting from double-use of syringes and other errors.

“Though we’ve never had an outbreak or known infection, establishing a culture of safety around these potential sources of infection is not just about procedure; it’s about trust and sleeping well at night,” Graves wrote.

To that end, Kent Hospital has stepped up safe injection education for its emergency department staff, including through staff meetings, e-mails, and a special presentation by Evelyn McKnight, a patient from Nebraska, whose health was severely affected by the problem.

McKnight, who was receiving treatment at her local hospital for a recurrence of breast cancer, contracted hepatitis C when a provider used one IV bag as a shared source of flush for several chemotherapy patients.

“You could have heard a pin drop as these stories were told to over 100 physician attendees,” Graves wrote.

In addition, hospital officials have reminded the ED staff in meetings and e-mails that “it is never acceptable to use the same needle or syringe more than one time to draw up or administer medications, and that all single-dose vials of medications in the ED are just that: to be used once and then discarded,” Graves told Drug Topics.

In other related measures, the hospital has attached reminder placards to the top of procedure carts in the ED, and it plans to hold a “grand rounds” presentation for a multidisciplinary audience, addressing all aspects of safe injection practices.

All of Kent’s ED staff has been supportive of the initiative and “incredulous that this sort of problem even existed,” Graves said.

“All staff has agreed to be much more vigilant not only about their own practices regarding safe injections, but also the practices of their colleagues,” he added.

— Christine Blank, Contributing Editor
Pharmacy benefit managers are fighting back at prescription drug copay discounts, cards, and similar discount offers. Earlier this year, CVS Caremark began blocking about 30 drugs whose manufacturers were offering copay coupons. Express Scripts is taking similar steps.

“There are two ways to address copay discounts from a PBM and payer perspective,” Everett Neville, Express Scripts vice president for pharma strategy told Drug Topics. “One is the use of mail order, because our mail-order pharmacies do not accept copay coupons. The other way — and we have been doing this for a number of years — is to not cover the nonformulary product, or to cover it at a 100% copay.”

Over half of Express Scripts’ clients have opted for the second strategy, Neville said. It is part of the ongoing battle between branded products and their generic equivalents. Plan sponsors typically put the new generic formulation on a preferred copay tier and increase the copay on the branded product to encourage use of the generic option, Neville said.

Manufacturers take their shot
Manufacturers offer patients copay coupons, cards, and similar products that reduce the brand-name copay to something near the generic copay level.

“These discounts have the effect of increasing utilization of the most expensive products in each therapeutic class,” said Mark Merritt, president and CEO of the Pharmaceutical Care Management Association (PCMA). “Sometimes it’s brand versus brand, sometimes it’s brand versus generic. These discounts are a marketing tool that encourages the utilization of more expensive products that sticks payors with the tab.”

The PhRMA study
Not quite, countered the Pharmaceutical Research and Manufacturers of America. “We strongly support the use of copay coupons, where permissible, as they can reduce out-of-pocket costs, eliminating financial barriers that may prevent patients from accessing or adhering to needed treatments,” said PhRMA senior vice president Matthew Bennett in a statement.

PhRMA cited an analysis by the Amundsen Group with four major conclusions:

- Copay card usage is not correlated with lower generic utilization in any major therapeutic class.
- Coupons are most often used by patients taking brands that are the least expensive for employers and insurers.
- Most PhRMA support for copay discounts goes into specialty or biologic products with no generic alternatives.
- The return on investment for drugmakers comes from increased adherence to therapies that have already been initiated.

If Massachusetts were to overturn its ban on copay coupons, plan sponsors would spend an additional $750 million on Rx purchases over the next decade.

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The PCMA study
PCMA offered its own analysis, conducted by Visante, with three conclusions:

- Copay coupons and similar strategies could boost prescription drug costs for drug plan sponsors by $32 billion over the next decade.
- Not enforcing the existing ban on copay coupons for Medicare Part D could add $18 billion to drug spending between 2012 and 2021.
- If Massachusetts were to overturn its existing ban on copay coupons, plan sponsors would spend an additional $750 million on prescription purchases over the next decade.

JAMA weighs in
The Journal of the American Medical Association has also stepped into the fray. David Grande, MD, MPA, Perelman School of Medicine and Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, concluded that copay cards for Lipitor (atorvastatin, Pfizer) lower costs for patients compared to the generic simvastatin. Copay cards for Crestor (rosuvastatin, AstraZeneca) increase patient costs compared to the generic statin. And copay cards for both products increase costs for insurers.

“Copay cards are good when patients have percentage copays and products are very expensive,” Neville said. “Say you have an orphan drug that costs $5,000 a month and your copay is 25%. That level of copay can significantly impact compliance. Copay cards can help patients afford the product and comply with the regimen. This is a small percentage of copay cards that we see, a significantly small minority.

“Most copay cards are used to get around formularies,” he continued. “It reduces the manufacturer’s incentive to pay rebates. Members stay on branded products longer at a higher copay than the generic and spend more out-of-pocket. And it drives up payer costs, which translate into higher premiums.”
In total, 2,637 retail pharmacies had questionable Part D billing in 2009, the OIG wrote. “While some of this billing may be legitimate, all pharmacies that bill for such extremely high amounts warrant further scrutiny.”

The good news in the report is that OIG concluded that just 4% of the 59,307 retail pharmacies that billed Medicare Part D in 2009 submitted questionable claims. The bad news is that some portion of that 4% almost certainly represents fraud and abuse.

“In any sector of healthcare, you will find fraudsters,” said John Coster, PhD, RPh, senior vice president for Government Affairs for the National Community Pharmacists Association. “We would support digging deeper into the data to see if these pharmacies are providing appropriate patient care or if they are scamming the system.”

Eight measures
The report does not directly charge pharmacies, independent or otherwise, with fraudulent or abusive practices. OIG noted that pharmacies serving pain clinic or hospital patients as well as those with older patients could have very legitimate reasons for billing outside national norms.

It simply says that 4% of pharmacies submitted claims that are questionable based on eight measures: the average amount billed per beneficiary, average number of prescriptions per beneficiary, average amount billed per prescriber, average number of prescriptions per prescriber, percent of prescriptions for Schedule II drugs, percent of prescriptions for Schedule III drugs, percent of prescriptions for brand name drugs, and percent of prescriptions for refills.

And of the pharmacies that submitted questionable billings, independents were eight times more likely than chain stores to show questionable charges.

Local singularities
Pharmacies in metro Miami were four times more likely to have dubious billings than in other parts of the country. The biggest problem: extremely high amounts per beneficiary. Ten Miami pharmacies billed an average of $8,000 or more per beneficiary, five times the national average. Miami pharmacies also billed for unusually high amounts of brand name drugs.

Pharmacies in Los Angeles and Detroit were about 2.5 times more likely to submit questionable billings. The major problem in Los Angeles was excessive brand-name billing. Detroit pharmacies overbilled for Schedule III products, most often hydrocodone-acetaminophen combinations.

Pharmacies in New York, Baltimore, and Tampa were twice as likely to submit questionable billings as the national average. New York saw major problems with excessive billings per beneficiary and a high percentage of brand-name drugs. In Baltimore and Tampa, the problem was with excessive Schedule II billings, primarily oxycodone (OxyContin, Purdue).

The report created a few immediate headlines linking independent pharmacy with fraud. Both the National Association of Chain Drug Stores and the Academy of Managed Care Pharmacy declined to comment on the findings.

While OIG said it would refer the questionable pharmacies to CMS for further investigation, the report said CMS’ own lack of oversight was the major culprit.

“Our findings indicate vulnerabilities in the oversight of the Part D program,” OIG wrote. “Prior reports have also found evidence of these vulnerabilities … Together, these findings call for a strong response to improve Part D oversight.”

CMS agreed that it needed to strengthen pharmacy oversight and review, provide additional guidance to Part D plan sponsors on monitoring pharmacy billing, further strengthen compliance plan audits, and follow up on questionable billings identified by the report.

The agency agreed in part with recommendations to require plan sponsors to refer potential fraud and abuse incidents for further investigation and to develop fraud and abuse risk scores for individual pharmacies.
Drug shortage crisis highlights importance of teamwork

The ongoing drug shortage crisis demands resourcefulness and communication among all health-system staff members, according to Agnes Ann Feemster, PharmD, BCPS, assistant director of clinical pharmacy and investigational drug services at the University of Maryland Medical Center in Baltimore.

Even with the severe recent shortages of certain chemotherapy and anesthesiology drugs, the medical center staff has always been able to obtain the needed medications for patients. “The slogan that drives our approach is ‘Collaboration, communication, and coordination,’” Feemster told Drug Topics.

100 shortages

Feemster described the medical center’s methods for success to U.S. Sen. Barbara Mikulski (D-Md.) and U.S. Rep. Elijah Cummings (D-Md.) during a roundtable discussion on prescription drug shortages presented earlier this year at the University of Maryland.

Drug shortages have nearly quadrupled over the past five years, and the medical center is currently “directly impacted” by 100 drug shortages, Feemster said. “The fact that we are unable to access critical drugs has the potential to impact patient care and patient safety,” she said.

In addition, the shortages are having a tremendous financial impact on hospitals, because most hospitals have increased staff hours to identify and coordinate alternative drugs, and then communicate about the issues. “We estimate that we spend 60 to 80 hours a week managing drug shortages,” Feemster said.

The varieties of medication in short supply may vary from week to week. According to Feemster, critical drugs that have been in short supply at the University of Maryland Medical Center in recent months have included calcium gluconate, sodium bicarbonate, etomidate, and the benzodiazepines. To date, the medical center has successfully handled the shortages. No critical patient has gone without his or her needed medication.

A multi-tiered approach

To handle the crisis, the medical center has employed a multi-tiered approach.

First, the medical center designated its Pharmacy and Therapeutics Committee as the group to oversee the drug shortage crisis on a daily basis. “We rely heavily on our physician members to identify alternatives and disseminate information,” Feemster said. Also, the hospital’s pharmacy team, which includes clinical pharmacists, the pharmacy buyer, the formulary management coordinator, and pharmacy managers, meets weekly to assess shortages.

“At the meeting, we review the supply level of a particular short medication and estimate how long the supply is expected to last. If we are nearing a critical point, we identify substitute drugs and discuss patient needs and priorities,” Feemster said.

For example, a medication that is in short supply may be centralized to one floor, to focus on the patients who critically need the drug and “to better manage the inventory that we have.”

The Pharmacy and Therapeutics Committee communicates regularly with the medical center’s physicians and nurses through e-mail and pop-up alerts in the center’s electronic medical records system. “The alert may state: ‘This product is critically low. Please use judiciously,’” Feemster said. Information on shortages also appears on the center’s pharmacy intranet home page, and pharmacists provide shortage updates at hospital staff committee meetings.

Import and swap

When a drug is nearing critically low levels, the pharmacy team communicates with prescribers and suppliers to determine alternative medications and/or sources of supply. “We explore every avenue. For example, we have imported drugs from Great Britain and Italy, if the FDA allows,” Feemster said.

In addition, the medical center staff works closely with neighboring health systems to purchase and trade medications when needed. “They may have a large supply of a drug that we need and vice versa,” Feemster said. For example, the medical center has arranged with an area hospital that if methotrexate is needed for a critically ill patient, that hospital will supply the medication, and vice versa.

Notably, the University of Maryland has not resorted to the gray market to fill shortages. “We can’t easily guarantee authenticity or integrity of the product on the gray market. As an organization, we decided we aren’t willing to accept the risk that a drug might be counterfeit or handled improperly,” Feemster said.
Better cleaning of patient rooms can reduce hospital-acquired infections

Hospitals and other healthcare settings have a choice when it comes to environmental cleaning. They can continue current patient-room cleaning practices that contribute to 100,000 fatalities yearly from hospital-acquired infections (HAIs), or they can introduce structured cleaning programs that reduce surface pathogens, reduce transmission, and reduce HAIs.

“Environmental surfaces are no different from the hands of healthcare workers, in terms of the transmission of pathogens,” said Salah Qutaishat, PhD, senior clinical advisor for infection prevention to commercial sanitation provider Divesey, Inc. “Current disinfection practices at most institutions are not effective. There is recent evidence that programs to improve environmental hygiene improve the efficacy of infection prevention programs and reduce the bioburden of pathogens.”

The hotel-like approach

The problem is that most hospitals take a hotel-like approach to cleaning patient rooms and other surfaces. Surfaces that appear to be dirty get cleaned, while surfaces that appear to be clean get only sporadic cleaning attention.

Workers responsible for cleaning patient rooms, bathrooms, and other care areas receive little or no training in environmental hygiene, Dr. Qutaishat said during a recent webinar from Pharmacy OneSource. Cleaning supervision is haphazard and usually based on visual inspection. Few institutions have implemented structured environmental cleaning programs, and even fewer validate their cleaning processes. It is, he said, a recipe for failure.

Recent studies based on environmental sampling show that appropriate levels of cleanliness and pathogen contamination are achieved on less than 40% of surfaces tested in three dozen acute-care hospitals. Structured interventions that include precise, step-by-step protocols, employee training, adequate supervision, surface testing and process validation, and regular data collection and analysis can boost successful surface cleaning to more than 80%.

“We are not doing a great job of environmental cleaning,” Dr. Qutaishat said. “We can improve environmental cleaning using a pragmatic, quantitative approach that is highly cost-effective.”

Standard cleaning processes are based on subjective visual assessment of surfaces. A more effective process focuses on regular cleaning of known high-touch surfaces that are most likely to harbor pathogens as well as terminal cleaning after each patient vacates the room.

Studies have identified 18 high-touch surfaces in patient rooms most likely to harbor pathogens. The highest pathogen load is typically found on remote controls, bed control panels, patient pull cord, toilet and nearby wall areas, faucet handles, and light switches.

Surface contamination is an enduring issue, Dr. Qutaishat noted. Patients in hospital rooms that previously housed a patient with an infection are at significantly higher risk of infection themselves. Methicillin-resistant *Staphylococcus aureus* can survive on environmental surfaces up to seven months, he noted. *E. coli* for 16 months. Norovirus remains viable for three weeks on environmental surfaces while severe acute respiratory syndrome, HIV, and influenza virus remain viable for about a week.

“The evidence is there that pathogens survive for a significant length of time even with cleaning,” he said. “Some of them are highly virulent. Norovirus doesn’t require a large number of pathogens for effective transmission even after a couple of weeks on a door handle or some other room surface.”

A joint effort

The Centers for Disease Control and Prevention published an environmental cleaning toolkit in 2010 as part of infection prevention efforts, Dr. Qutaishat said. The hospital cleaning program should be a joint effort between infection prevention and environmental services. Each department should have clearly defined responsibilities, with structured staff training and direct measurement of cleaning results.

Swab and culture remains the gold standard to test for surface pathogens, but the method is slow and expensive. Fluorescent markers or ATP testing can identify surfaces inadequately cleaned, but cannot verify the presence of pathogens.

Quaternary ammonium, bleach, and accelerated/activated hydrogen peroxide remain the standard cleaning agents, but it is time to retire reusable cotton wipes. Pathogens can survive on the wipes and be moved around the hospital the next time the cloth is reused. Disposable microfiber wipes are much more effective cleaning tools, Dr. Qutaishat said.
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Consider these common prescriptions: Sliding-scale insulin for a 68-year-old woman with diabetes; lorazepam (Ativan) for an 82-year-old man experiencing delirium; nitrofurantoin for a 78-year-old woman with a urinary tract infection.

Most pharmacists would be likely to accept the scripts without a second thought. Bad decision.

"Something needs to be said about the use of these agents in older adults," said Todd Semla, PharmD, associate professor, Clinical Medicine–General Internal Medicine and Geriatrics, and Psychiatry and Behavioral Sciences, Feinberg School of Medicine, Northwestern University. Semla is also a clinical pharmacy specialist with the Department of Veterans Affairs in Chicago. "Take benzodiazepines. The evidence is that short-acting benzodiazepines are also associated with falls, just like the longer-acting agents in the class."

What does Semla know that other pharmacists don’t? "The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults."

He co-chaired the panel that revised the Beers Criteria under the aegis of the American Geriatrics Society (AGS) earlier this year. The Criteria list more than a dozen drugs and therapeutic classes that should be used with caution in older adults — as well as dozens of agents that should be avoided in most geriatric patients.

"One of the overarching achievements is that we took on an evidence-based approach to evaluating drugs that may be inappropriate in older adults," Semla said. "Our ultimate goal with the Beers Criteria is to improve the care of our patients."
**Potentially inappropriate**

The Beers Criteria were first published by geriatrician Mark Beers, MD, in 1991. The initial list focused on medications commonly prescribed to nursing-home patients, for whom the potential risks outweighed the benefits. The Criteria are not a never-use list, but a use-with-caution list.

The reality that use of benzodiazepines increases the risk of adverse events does not mean that these medications should never be used. It means they should be used only after consideration of alternative agents. Benzodiazepines may be appropriate for seizure disorders, rapid eye movement sleep disorders, benzodiazepine withdrawal, ethanol withdrawal, severe generalized anxiety disorder, periprocedural anesthesia, and end-of-life care, but those uses are rare.

“The Beers Criteria have improved practice and patient outcomes by increasing awareness of drugs that should be avoided in most patients and most settings,” said revision panel co-chair Donna Fick, PhD, RN, professor of nursing and medicine, School of Nursing and College of Medicine, Department of Psychiatry, The Pennsylvania State University, University Park, Penn. “I want every prescriber to think twice about giving Ativan to an 80-year-old for delirium.”

Beers revisions in 1997 and 2003 expanded the scope of the Criteria to include medications that are potentially inappropriate for patients age 65 and older, regardless of the care setting. Long-term-care pharmacists and geriatricians know and use the Criteria, Fick said, but awareness among other health professionals is spotty.

“When I walk down the halls of any community hospital, pharmacists, long-term-care pharmacists, and even primary care physicians may be unaware of the Beers Criteria,” she said.

“Other health professionals are often not aware of the Beers Criteria, and those who are aware may not be fully familiar with the revised criteria,” Fick said. “The reality is that these criteria are not widely known or used. The purpose of this article is to increase awareness of the Beers Criteria for patients age 65 and older.”

**Drugs older adults should avoid**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-generation antihistamines</td>
<td>Highly anticholinergic, clearance reduced with advanced age, tolerance develops when used as hypnotic. Greater risk of toxicity.</td>
</tr>
<tr>
<td>Antiparkinson agents benzotropine, trihexyphenidyl</td>
<td>More effective agents available.</td>
</tr>
<tr>
<td>Antispasmodics, select</td>
<td>Highly anticholinergic, uncertain effectiveness.</td>
</tr>
<tr>
<td>Antithrombetics: dipyridamole (oral, short-acting only), ticlopidine</td>
<td>Safer, effective agents available.</td>
</tr>
<tr>
<td>Anti-infective nitrofurantoin</td>
<td>Potential for pulmonary toxicity, safer alternatives available, lack of effectiveness in impaired renal function.</td>
</tr>
<tr>
<td><strong>Cardiovascular:</strong></td>
<td></td>
</tr>
<tr>
<td>Alpha blockers, select</td>
<td>High risk of orthostatic hypotension.</td>
</tr>
<tr>
<td>Alpha agonists, central</td>
<td>High risk of adverse CNS effects.</td>
</tr>
<tr>
<td>Antiarrhythmic (class Ia, Ic, III)</td>
<td>Rate control yields better balance of benefit and harm.</td>
</tr>
<tr>
<td>Disopyramide</td>
<td>May induce heart failure.</td>
</tr>
<tr>
<td>Dronedarone</td>
<td>Rate control preferred, worse outcomes reported with atrial fibrillation or heart failure.</td>
</tr>
<tr>
<td>Digoxin &gt;0.125 mg/d</td>
<td>No additional benefit with higher doses and may increase risk of toxicity.</td>
</tr>
<tr>
<td>Nifedipine immediate release</td>
<td>Potential for hypotension, risk of myocardial ischemia.</td>
</tr>
<tr>
<td>Spironolactone &gt; 25mg/d</td>
<td>In heart failure, higher risk of hyperkalemia.</td>
</tr>
<tr>
<td><strong>CNS agents:</strong></td>
<td></td>
</tr>
<tr>
<td>Tertiary TCAs</td>
<td>Highly anticholinergic, sedating, cause orthostatic hypotension.</td>
</tr>
<tr>
<td>Antipsychotics, first generation and atypicals</td>
<td>Increased risk of stroke and mortality in dementia.</td>
</tr>
<tr>
<td>Thoridazine, Mesoridazine</td>
<td>Highly anticholinergic, risk of QT-interval prolongation.</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>High rate of physical dependence, tolerance of sleep benefits, risk of overdose at low dosages.</td>
</tr>
<tr>
<td>Benzodiazepines: short-, intermediate-, and long-acting</td>
<td>Increased sensitivity to the class, increased risk of cognitive impairment, delirium, falls, fractures, motor vehicle accidents.</td>
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</tbody>
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Continued on page 24
Beers

Continued from pg. 23

physicians, nurses, therapists — none of them has heard of the Beers Criteria,” she said. “Part of our work with the revision is to help healthcare professionals recognize that the Criteria can be a simple, highly effective tool to improve patient care in any setting.”

Pharmacists and clinicians in nearly all care settings deal with older patients, said Marsha Meyer, PharmD, senior care pharmacist and founder of Senior MedHelp in Irvine, Calif. Nearly half of all hospital admissions are associated with an adverse drug event, she noted. Older patients are a growing segment of pharmacy practice in the community and in health systems. “Baby boomers are coming into Medicare age,” she said. “Every pharmacist sees older patients every day. The reality is that more than half of older adults have two or more chronic diseases. And with chronic disease comes increased medication risks. The Beers Criteria are a great addition to the tool kit that we all use.”

On and off the list
The revised Criteria offer three significant advantages over previous versions of the guide.

The most obvious improvement is that the list has been brought up to date.

Dozens of new drugs have been approved since the last revision in 2003. “There has been a lot of literature and data [produced] since 2003,” noted panel member Sunny Linnebur, PharmD, associate professor, Department of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus, Aurora, Colo. “In many cases, it’s not the drug, but it is the dose that is important to pay attention to.”

For example, boosting spironolactone (Aldactone) dosing above 25 mg/day increases the risk of hyperkalemia. The use of sliding-scale insulin increases the risk of hypoglycemia without improving hyperglycemia.

“We are not recommending avoiding insulin; we are recommending avoiding sliding-scale insulin,” Linnebur said. “Basal insulin and fixed doses of short-acting insulin may be entirely appropriate for older adults.”

**Drugs older adults should avoid** (continued)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rationale</th>
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<tr>
<td><strong>Endocrine agents:</strong></td>
<td></td>
</tr>
<tr>
<td>Androgens, desiccated thyroid</td>
<td>Potential for cardiac problems, androgens contraindicated in prostate cancer.</td>
</tr>
<tr>
<td><strong>Estrogens, with or without progestins</strong></td>
<td>Carcinogenic potential, lack of cardioprotective or cognitive protection effect.</td>
</tr>
<tr>
<td><strong>Growth hormone</strong></td>
<td>Edema, arthralgia, carpal tunnel syndrome, gynecomastia, impaired fasting glucose.</td>
</tr>
<tr>
<td><strong>Insulin, sliding scale</strong></td>
<td>Higher risk of hypoglycemia without improvement in hyperglycemia in all care settings.</td>
</tr>
<tr>
<td><strong>Megestrol</strong></td>
<td>Risk of thrombotic events, mortality.</td>
</tr>
<tr>
<td><strong>Sulfonylureas, long-duration</strong></td>
<td>Risk of prolonged hypoglycemia.</td>
</tr>
<tr>
<td><strong>Gastrointestinal:</strong></td>
<td></td>
</tr>
<tr>
<td>Metoclopramide</td>
<td>Extrapyramidal effects, including tardive dyskinesia, especially in older, frail adults.</td>
</tr>
<tr>
<td><strong>Mineral oil, oral</strong></td>
<td>Potential for aspiration and adverse effects.</td>
</tr>
<tr>
<td><strong>Trimethobenzamide</strong></td>
<td>Among least effective antiemetics; can cause extrapyramidal adverse effects.</td>
</tr>
<tr>
<td><strong>Pain:</strong></td>
<td></td>
</tr>
<tr>
<td>Meperidine</td>
<td>Ineffective as oral analgesic in common dosages; may cause neurotoxicity.</td>
</tr>
<tr>
<td><strong>Non-COX-selective NSAIDs, Indomethacin, ketorolac</strong></td>
<td>Increased risk of GI bleeding. Indomethacin has most adverse effects.</td>
</tr>
<tr>
<td><strong>Pentazocine</strong></td>
<td>CNS adverse effects, mixed agonist/antagonist</td>
</tr>
<tr>
<td><strong>Skeletal muscle relaxants</strong></td>
<td>Anticholinergic adverse effects, sedation, risk of fracture. Questionable effectiveness at doses tolerated by older adults.</td>
</tr>
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Marsha Meyer

Continued from pg. 23
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Kit also contains:

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†Combing result demonstrated in a laboratory study performed by trained testers.

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The second advantage has to do with the way drugs were evaluated. Past panels used a Delphic method to reach consensus, Semla said. The 2012 revisions rely on evidence.

Each recommendation includes the quality of the evidence and the strength of the recommendation. For the first time, the AGS website includes links to the evidence (http://americangeriatrics.org/files/documents/beers/2012AGSBeersCriteriaCitations.pdf) for pharmacists, prescribers, and patients who want the details.

“It is important to look at the quality of the evidence and the strength of each recommendation,” Linnebur said. “You can use the data tables as necessary, but most of what you need is there in the recommendation tables.”

The third advantage is publicity. AGS has committed to publishing, updating, and disseminating the new version of the Criteria.

“It helps to have the Criteria under the imprimatur of the AGS,” said panel member Michael Steinman, MD, associate professor of medicine in the Division of Geriatrics at the University of California, San Francisco, and the San Francisco VA Medical Center. “They are a leading voice in gerontology. Simply putting out the list isn’t sufficient by itself to get it used.”

Used for what?
The panel is also concerned about how the Beers Criteria are used. The goal, Steinman said, is to improve clinical care by reducing the inappropriate use of medications.

The Criteria have been incorporated into some drug utilization review programs. And while it is good to have pharmacists catch potentially inappropriate scripts, it would be better if those scripts were never written. He would like to see the Beers Criteria integrated into electronic health records (EHR) and e-prescribing systems.

“Once a drug is prescribed, it is very difficult to reel it back in,” Steinman said. “Ideally, the list would be used before prescribing in drug selection as part of the EHR. There are occasions when any drug on the list could be the ideal drug for a particular patient, so having a caution is appropriate as long as it comes in the clinical context.”

Inappropriate use of the Beers Criteria is another concern. The Centers for Medicare and Medicaid Services (CMS) and some private payers use the Criteria to evaluate the quality of care delivered by practitioners. Individual prescribers and their institutions may be penalized for exceeding thresholds for the use of Beers-listed medications.

Both panel co-chairs have spoken against such punitive uses, but payers still use the Criteria in quality assessments that can affect reimbursement. The American Society of Health-System Pharmacists (ASHP) opposes use of the Beers by CMS and other accreditation or quality improvement organizations as the sole criteria to assess the appropriateness of prescribing for geriatric populations.

“We are pleased that the Beers Criteria have been revised,” said Cynthia Reilly, BS Pharm, director of the Practice Development Division at ASHP. “It provides a very useful clinical tool,” she continued. “It is the use of the Criteria as a reimbursement criterion that we have problems with. Each patient needs to be addressed on an individual basis, and these quality measures look at pooled data, not patient-specific measures or outcomes.”

CMS is unlikely to abandon the Beers Criteria as a quality measure, Reilly added, at least in the short term. ASHP, the revision panel, and others are still pushing.

“The long-term application of the list is what matters,” Steinman said. “What matters is that people use it wisely to guide clinical decisions.”

Drugs older adults should use with caution

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin for primary prevention</td>
<td>No evidence of benefit &gt; age 80.</td>
</tr>
<tr>
<td>Dabigatran</td>
<td>Greater risk of bleeding than warfarin &gt; age 75, lack of evidence for safety, efficacy in impaired renal function.</td>
</tr>
<tr>
<td>Prasugrel</td>
<td>Greater risk of bleeding, but risk may be offset by benefits in highest-risk older patients with prior MI or diabetes mellitus.</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>May exacerbate or cause syndrome of inappropriate diuretic hormone secretion or hyponatremia. Must monitor sodium level closely.</td>
</tr>
<tr>
<td>Vasodilators</td>
<td>May exacerbate episodes of syncope in individuals with history of syncope.</td>
</tr>
</tbody>
</table>

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Contributing Editor Fred Gebhart works all over the world as a freelance writer and editor, but his home base is in San Francisco.
Fondaparinux safe in renal impairment

Patients with renal impairment often need prophylaxis for venous thromboembolism (VTE); however, clinical trial data on anticoagulants are limited in this population.

A recently published prospective study examined the safety and efficacy of fondaparinux in patients with a creatinine clearance (CrCl) of 20 to 50 mL/min. Patients who were undergoing total hip replacement, total knee replacement, or hip fracture surgery received fondaparinux thromboprophylaxis at a reduced dose of 1.5 mg daily. Main clinical outcomes were bleeding (major/clinically relevant non-major), symptomatic VTE, and death. A total of 442 patients (median age, 82 years) with a mean CrCl of 39 mL/min received fondaparinux 1.5 mg for a mean duration of 16 days.

Rates of major bleeding, clinically relevant bleeding, and symptomatic VTE were 4.5%, 0.5%, and 0.5%, respectively, at postoperative day 10. No incidences occurred of fatal bleeding, bleeding into a critical organ, pulmonary embolism, or proximal deep-vein thrombosis. Corresponding rates at 1 month were 5.2%, 0.7%, and 0.7%, respectively, with a 1-month mortality of 2.3%.

Under conditions reflecting “real-world” routine clinical practice, this large clinical, prospective study provides data for the first time on the bleeding and VTE risks of thromboprophylaxis with fondaparinux 1.5 mg after major orthopedic surgery in renally impaired patients.


Aspirin vs. warfarin for stroke prevention in CHF

Congestive heart failure (CHF) is associated with an increased risk of thrombus formation and is accompanied by a 2- to 3-fold increased risk of stroke. Stroke in CHF patients is associated with poor outcome and higher mortality. For these reasons, patients with CHF are often treated with warfarin to prevent blood clots.

A recent international double-blind, study of 2,305 patients with heart failure and normal sinus rhythm found that aspirin works just as well as warfarin. In this study, half of the subjects were given regimens of warfarin and placebo, while the other half received aspirin and placebo warfarin. The patients were followed for up to 6 years, with the primary outcome defined as time to the first event in the composite end point of ischemic stroke, intracerebral hemorrhage, or death.

Overall, whether patients were treated with warfarin or aspirin, there was no significant difference in the primary outcome (7.47 events/100 patient-years in the warfarin group vs 7.93 events/100 patient-years in the aspirin group; P=.40). Patients who took warfarin were significantly less likely to have a stroke, but that advantage was negated by an increased likelihood of gastrointestinal bleeding and other hemorrhages. There were no significant differences in rates of myocardial infarction or hospitalizations for heart failure.


tPA safe in patients on warfarin

An analysis of data from the American Heart Association Get With The Guidelines (GWTG)-Stroke Registry shows that acute ischemic stroke patients on warfarin with an international normalized ratio (INR) <1.7 can safely receive intravenous tissue plasminogen activator (tPA) without an increased risk of symptomatic intracranial hemorrhage (sICH).

A separate analysis of patients with ischemic stroke receiving warfarin in the GWTG-Stroke Registry showed that about 48% of warfarin-treated tPA-eligible patients with acute ischemic stroke do not receive tPA. Intravenous tPA remains the only effective treatment to improve stroke outcomes.

Current guidelines recommend intravenous tPA for ischemic stroke in warfarin-treated patients when the INR is <1.7. Yet there is considerable debate regarding the risk of sICH in warfarin-treated patients and a lack of safety data.

Study authors analyzed data on 23,437 patients with acute ischemic stroke who received tPA in more than 1,200 GWTG-Stroke hospitals between April 1, 2009, and June 30, 2011. Among these were 1,802 patients (7.7%) receiving warfarin prior to admission. Overall, 1,107 patients (4.7%) developed sICH after receiving tPA. Warfarin-treated patients were found to have a higher overall unadjusted rate of sICH relative to nonwarfarin-treated patients (5.7% vs 4.6%; P<.001). After risk adjustment, however, warfarin use was not an independent predictor of sICH risk.

The researchers cautioned that further study is needed to clarify the effectiveness and safety of tPA for patients beyond the recommended INR range of <1.7.

The pharmacist as public health advocate: Enhancing immunization rates

Chasity M. Shelton, PharmD, BCPS, BCNSP
Assistant Professor, Department of Clinical Pharmacy, University of Tennessee College of Pharmacy, Memphis, Tennessee

Stephan Foster, PharmD, FAPhA
Professor and Vice Chair, Department of Clinical Pharmacy, University of Tennessee College of Pharmacy, Memphis, Tennessee

Preventable infectious diseases continue to be a significant source of morbidity, mortality, and healthcare resource utilization throughout the developed world. In the United States alone, influenza-related mortality averaged 36,000 cases per season during the 1990s. Moreover, the mean number of patients hospitalized due to influenza from 1979 to 2001 amounted to an estimated 226,000 annually.

During pandemics, such as the recent H1N1 outbreak, complications and hospitalization rates can increase dramatically. Another common pathogen, Streptococcus pneumoniae, causes a variety of infections ranging in severity from noninvasive to life-threatening. In 2004, an estimated 4 million cases of pneumococcal disease occurred in the United States, resulting in 22,000 deaths and 445,000 hospitalizations. Persons most likely to be severely
Abstract

Immunization is fundamental to lessening the occurrence of vaccine-preventable infectious diseases but is thwarted by low vaccination rates throughout different regions of the United States and across various patient strata. In the mid-1990s, pharmacists were recruited to help bolster vaccination coverage rates by providing an accessible, convenient source for immunization education and administration, as well as helping to facilitate the vaccination efforts of other healthcare providers.

Pharmacists have taken on this challenge, with the assistance of pharmacy technicians and students. As advocates of public health through immunization, pharmacists have implemented numerous strategies to build public awareness, identify patient vaccination needs, and provide vaccination services. These efforts have been rewarded by improved vaccination rates. Collaboration with local immunization coalitions and other community groups has allowed pharmacists to reach underserved and in-need patient populations. The public has now embraced pharmacists as immunizers, as evidenced by the substantial, ever-growing proportion of influenza vaccinations administered by pharmacists each year.

Educational programs have trained more than 175,000 pharmacists in the fundamental, mechanistic, and practical aspects of immunization. The need remains to involve additional pharmacists in immunization advocacy, expand vaccine offerings available to pharmacists, and equalize pharmacist recognition as immunizers across states and healthcare plans.

affected by infectious diseases include young children, the elderly, and those with compromised immune systems or comorbidities (e.g., cardiovascular disease, respiratory disease). In select populations, the risk of less common viral-borne diseases, such as hepatitis B and shingles, is substantial.

Immunization is a key to controlling infectious diseases and maintaining population health. As a nation, however, we continue to fall short of immunization targets. For the 2010–2011 influenza season, only the states of Massachusetts, Rhode Island, and South Dakota reported vaccination coverage rates exceeding 51%. Overall, for the United States the seasonal influenza vaccination coverage was 43%. The percentage of high-risk, working-age adults who received the influenza vaccine was highly variable, ranging from 33.7% in Alaska to 68.4% in South Dakota. Limited improvements in vaccination coverage were observed in comparison with the previous year. The target of Healthy People 2020 is to achieve annual influenza vaccination rates of 80% to 90%, depending on the population in question.

Lack of adequate immunization is particularly notable among adults. During childhood, compulsory vaccination for public school admission and regular visits to the pediatrician ensure a certain level of compliance. Influenza vaccination coverage rates are appreciably higher among children age 6 months to 17 years than among adults age 18 years and older. Pneumococcal immunization coverage among U.S. citizens age 18 to 46 years with an indication for vaccination was only 17.4% in 2009, leaving approximately 59 million working-age adults at risk. The target established by Healthy People 2020 for this population is 60% vaccination coverage. For persons 65 years and older and for institutionalized adults, the pneumococcal vaccination coverage goal is 90%. In addition, more than half of high-risk adults age 19 to 49 years evaluated in 2010 had never been vaccinated against hepatitis B.

Evolution of pharmacist involvement

Pharmacist involvement in vaccination has gradually evolved from strictly a source of storage and distribution to full engagement in education, distribution, administration, and tracking. Following formal acknowledgment by the U.S. Department of Health and Human Services of the pharmacist’s role in vaccination, which occurred in the mid-1990s, recognition of pharmacists as immunizers was not immediately universal. States independently determined the level at which pharmacists could be involved. By 1999, 22 states allowed pharmacists to administer the influenza vaccine, but it was not until 2009 that this privilege extended to all 50 states.

The value of pharmacists as immunizers is evidenced by public utilization, which continues to grow. Survey data suggest that between 17 and 25 million doses of influenza vaccine were administered by pharmacists during the 2010–2011 season. Early comparisons of regions where pharmacists were permitted vs. not permitted to provide vaccinations demonstrated greater improvements in influenza vaccination rates associated with pharmacist involvement in administration.

Active participation by pharmacists has been a key driver in the move toward provision of vaccinations at nontraditional sites. During the 2010–2011 season, 18.4% of influenza vaccines were administered in stores — a notable increase from the reported percentages for adult in-store vaccinations in 1998–1999 (5%) or 2006–2007 (7%). The importance of nontraditional vaccination settings as a means of increasing vaccine accessibility was given greater weight by the Centers for Disease Control and Prevention (CDC). The Advisory Committee on Immunization Practices (ACIP) expanded the recommendation for influenza vaccination to include everyone age 6 months or older, which was instituted in 2010. This type of universal coverage would not be feasible if relegated to medical settings alone.

The expertise of the pharmacist, including that of vaccine administration, is a valuable asset to pandemic responses, such as the 2009 H1N1 vaccine initiative. As the first influenza pandemic since 1968, H1N1 was the inaugural testing ground for the immunizing pharmacist. The imperative to provide H1N1 vaccination across the breadth of the U.S., population within a relatively short time frame prompted a sizeable increase in pharmacist-administered vaccinations. Partnerships created between public health agencies and vaccination providers during the H1N1 pandemic have proved enduring.

Convenience and accessibility are among the chief advantages of involving pharmacists in immunization programs. Pharmacists interact with a large subset of the population on
a regular basis. It has been estimated that the number of people who enter a pharmacy during a single week is roughly equivalent to the total U.S. population. Number and location of sites, extended store hours, and short waiting periods favor pharmacies over the physician’s office as vaccination resources for many individuals. From the perspective of healthcare resource utilization, vaccination in nonmedical settings actually confers a cost advantage. Compared with vaccinations administered during scheduled primary care visits or at mass vaccination clinics, pharmacist-provided services have been shown to be the most cost-effective.

Obstacles do exist to the implementation of a pharmacy-based immunization program. The most common barrier expressed by pharmacists was lack of time; they are too busy. Other perceived barriers involve training, legal liability, space availability, level of reimbursement, staff support, management support, physician support, reporting requirements, and limitations based on state laws.

Healthcare-system constraints may also drive utilization of pharmacist-provided vaccination services. Such aspects as storage, handling, and cost considerations are barriers to stocking certain vaccines for physicians. Herpes zoster vaccine, for example, is both difficult to maintain because of the requirement for frozen storage in a separate sealed compartment and is expensive to the patient or difficult to reimburse (herpes zoster vaccine is covered under Medicare Part D). Survey data indicate that physicians often refer patients to pharmacies to obtain and receive the vaccination for herpes zoster, largely because of cost and reimbursement issues.

Pharmacists should discourage the practice known as “brown-bagging,” wherein patients obtain the vaccine from their pharmacist for later administration by their physician.

**Roles of the pharmacist**

Pharmacy practice has grown beyond the primary function of medication dispensation and information, with pharmacists now taking an active part in health screening, preventive care, and, to a lesser extent, public health advocacy. Establishment of the pharmacist as an advocate, facilitator, and immunizer by the American Pharmacists Association (APhA) in 1996 has fostered tremendous growth in the public health aspect of pharmacy practice, and with it, the role of the pharmacist in vaccination promotion and administration continues to evolve.

Changes reflect not only an increased emphasis on pharmacist involvement but also an appreciation for differences in the balance between these functions that is dictated by the nature of the pharmacist’s environment. Health-system pharmacists, for example, have a greater mandate for screening than for vaccine administration and reach a different audience than do community-based pharmacists (Table 1, page xx). Yet the goal in both cases is the same: Prevent the spread and sequelae of infectious diseases through improvement of immunization rates.

As **educators**, pharmacists are called on to encourage vaccination through disseminating guidance on the need for immunization, dispelling myths, and communicating accurate information on the benefits and risks associated with vaccines.

For the community-based pharmacist, this predominantly applies to addressing the needs of the general public, whereas the health-system pharmacist educates patients, their families, and healthcare workers. The APhA calls on pharmacists to direct their efforts toward diseases that have the greatest impact on public health, among which are influenza, pneumococcal diseases, hepatitis B, and herpes zoster. It should be noted, however, that disease risk is not homogenous within the population; high-risk subgroups need to be identified to allow for appropriate vaccination recommendations.

**Screening**, including both the assessment of an individual’s vaccination needs and ascertaining the presence of any contraindications or precautions, has become a routine component of daily practice for many pharmacists. Opportunities for screening abound, such as when an individual is filling a prescription, at hospital admission, on diagnosis of a high-risk condition, prior to certain medical procedures, and during clinic appointments.

The Center for Medicare and Medicaid Services (CMS) has instituted a quality improvement measure to ensure that all hospital inpatients and nursing home residents be assessed for influenza and pneumococcal immunization and provided the necessary vaccination, unless contraindicated or refused.

In the hospital setting, pharmacists are often involved in gathering patient immunization histories and have actually been shown to generate more complete medication and immunization histories than other hospital personnel. One assessment reported that complete immunization histories were obtained for 100% of patients when clinical pharmacists were involved versus only 18% of patients when the information was acquired by emergency department personnel. Prior to the inclusion of pharmacists as immunizers, facilitation through hosting other healthcare providers who administer vaccinations was a common method of involvement.

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**Table 1**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1850</td>
<td>Pharmacists oversee depots for diphtheria antitoxin</td>
</tr>
<tr>
<td>1900</td>
<td>Pharmacists distribute smallpox vaccine to physicians</td>
</tr>
<tr>
<td>1950</td>
<td>Pharmacists educate physicians and the public about vaccines</td>
</tr>
<tr>
<td>2000</td>
<td>All 50 states allow pharmacists to administer vaccines</td>
</tr>
</tbody>
</table>

**Source:**Refs 1-6
This is still a viable approach, particularly for pharmacists who do not wish to administer vaccines. Nonimmunizing pharmacists can also participate in immunization advocacy through educational activities, patient screening and counseling, documentation, and other administrative tasks. For certified immunizing pharmacists, the facilitation role could take the form of allowing pharmacy students to gain practical vaccination experience.

With the addition of Maine in 2009, qualified pharmacists gained the authority to administer vaccinations in all 50 states. The scope of vaccination privileges, however, is state specific. State regulations dictate the types of vaccines that may be given, age restrictions, and the process by which pharmacists can administer vaccinations. The latter refers to the need for a prescription, protocol, or standing order.

Standing orders allow for the assessment of immunization needs and administration of vaccines for patients who meet certain criteria without an individual mandate from a physician for each patient. Standing orders can be used in a variety of settings, from private practice to hospitals and long-term-care facilities. Implementation of standing orders has been shown to increase vaccination rates and is endorsed by organizations such as the ACIP, CMS, and American Society of Health-System Pharmacists (ASHP). Standing order templates and other relevant information are available through the Society of Teachers of Family Medicine (www.immunizationed.org) and the Immunization Action Coalition (www.immunize.org).

Vaccination of healthcare workers. Although the task of vaccinating patients does not typically fall to health-system pharmacists, they may be involved in vaccination of healthcare workers—a group with unexpectedly low vaccination rates. Healthcare workers regularly encounter high-risk patient populations, which increases both their risk of contracting a vaccine-preventable infectious disease and the possibility of transmitting disease to their patients. Indeed, substantial reductions in risk of influenza among hospitalized patients and nursing-home residents have been achieved through universal vaccination coverage among healthcare workers.

Despite recommendations that healthcare workers be vaccinated against influenza each year, survey data indicate a vaccination coverage rate of only 63.5% among healthcare workers during the 2010–2011 influenza season. This represented only a modest increase from the 61.9% vaccination coverage of the 2009–2010 influenza season.

Hepatitis B is another important vaccination for healthcare personnel, with a targeted coverage rate of 90%, approximately 40% higher than was reported in 2008. Time constraints and misconceptions about vaccines are barriers to healthcare workers seeking vaccination. To increase healthcare-worker access, health-system pharmacists have helped to organize vaccination clinics for employees and bring services directly to patient-care units, employee departments, and outpatient clinics, thus negating time constraints.

To be effective advocates of immunization and prevent transmission of infectious diseases to their clients, pharmacists must also receive recommended vaccinations. Overall, reported influenza vaccination rates among pharmacists are higher than the general public or other healthcare workers (78% vs 43% and 64%, respectively), but this figure can still be improved.

**Documentation.** Vaccinations should be documented in several ways. First, the pharmacist has a duty to report to the patient’s primary care provider (PCP) or to the local health department that a vaccination has been given. Communication with the PCP is fundamental to maintaining a “medical home” or “patient-centered medical home” model of care, wherein a personal physician coordinates care and tracks information over time and between multiple sources. Immunization data may also be submitted to an immunization information system or registry, which are centralized record repositories accessible to healthcare providers. A list of state immunization information systems can be found on the CMS website (www.cdc.gov/vaccines/programs/IIS).

Second, pharmacists should maintain permanent immunization records and encourage patients to keep their own immunization records up to date.

Last, pharmacists should report vaccine-related adverse events to the PCP and to the Vaccine Adverse Event Reporting System (VAERS). VAERS submissions can be made online (www.vaers.hhs.gov/index), by fax (1-877-721-0366), or through the mail. Billing and reimbursement for pharmacist-provided vaccinations can be somewhat challenging given differences in third-party payer policies. Moreover, not all vaccination coverage runs through the same channels. Influenza, pneumococcal, and hepatitis B vaccines are covered under Medicare Part B; all other vaccines are covered under Medicare Part D.

**TABLE 1**

<table>
<thead>
<tr>
<th>Vaccination-related Functions of Community and Health-system Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Community Pharmacists</strong></td>
</tr>
<tr>
<td>Dispel myths and educate the public</td>
</tr>
<tr>
<td>Screen patients for vaccination needs</td>
</tr>
<tr>
<td>Encourage patients to keep an up-to-date immunization record</td>
</tr>
<tr>
<td>Host other healthcare providers who administer vaccinations</td>
</tr>
<tr>
<td>Bring vaccinations to the community</td>
</tr>
<tr>
<td>Immunize the general public</td>
</tr>
<tr>
<td>Maintain a permanent immunization record</td>
</tr>
<tr>
<td>Communicate vaccination to the patient’s primary care provider and other necessary parties</td>
</tr>
<tr>
<td>Report adverse events</td>
</tr>
</tbody>
</table>

Source: Ref 19-21

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** Billing and Reimbursement** for pharmacist-provided vaccinations can be somewhat challenging given differences in third-party payer policies. Moreover, not all vaccination coverage runs through the same channels. Influenza, pneumococcal, and hepatitis B vaccines are covered under Medicare Part B; all other vaccines are covered under Medicare Part D.
TABLE 2

PARTICIPATION OF PHARMACY TECHNICIANS AND PHARMACY STUDENTS IN VACCINATION PROGRAMS

<table>
<thead>
<tr>
<th>Task</th>
<th>Pharmacy technicians</th>
<th>Pharmacy students</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen patients and assemble pre-vaccination paperwork</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Disseminate immunization awareness materials (fliers, brochures, etc.)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Assist with vaccination documentation</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Administer vaccines under the supervision of a qualified pharmacist</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contribute to the establishment of pharmacy-based vaccination programs</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Organize vaccination events</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Source: Ref. 30

It is therefore vital that pharmacists familiarize themselves with compensation routes that may be available to their customers to minimize unnecessary out-of-pocket expenses. Options for reimbursement are discussed as part of the APhA training curriculum for immunization certification, and additional information on Medicare-related reimbursement issues, and concerns about legal liability.

Involvement of pharmacy technicians and pharmacy students

There are many ways in which pharmacy technicians and pharmacy students can contribute to immunization advocacy and vaccination programs (Table 2). Although they are not permitted to administer vaccines, pharmacy technicians are a valuable resource for performing the necessary groundwork, such as identifying candidates for vaccination, administering screening questions, obtaining insurance information, and clarifying which vaccine(s) the patient wishes to receive.

Pharmacy technicians can also help build public immunization awareness through adding informational fliers or stickers to prescription bags and may be called on to assist in documentation by transmitting vaccination information to the PCP or health department registries.

In addition to the functions listed previously for pharmacy technicians, in most states pharmacy students can also provide vaccinations with the oversight of a certified pharmacist immunizer. It has been observed that in some pharmacy practices, students are underutilized for vaccine administration, presumably because of a failure to realize the capabilities of students in this area. Many pharmacy students are trained in immunization and participate in vaccination programs as part of their education.

One such opportunity for involvement is the student-created initiative “Operation Immunization: The Nation’s Student Pharmacists and Practitioners Protecting the Public Health,” which was developed in 1997 by the APhA Academy of Student Pharmacists (APhA-ASP) and the Student National Pharmaceutical Association (SNPhA). Occurring each fall, this initiative allows pharmacy students to advocate for immunization, educate the public, and assist pharmacist immunizers and other healthcare providers to administer vaccines.

Another role that has been suggested for pharmacy students is in the establishment of pharmacy-based vaccination programs. In this capacity, students can assist pharmacists by researching immunization resources, contacting local health departments and immunization coalitions, acquiring the necessary educational materials and forms, and evaluating methods for communicating with customers.

Perceptions and acceptance of the pharmacist immunizer

Pharmacists generally view vaccination as a positive expansion of their practice. In a 2009 survey of community pharmacists in Arkansas, 79% of respondents believed that vaccination administration has been a means of advancing the profession. Although the majority of pharmacists who receive immunization certification go on to administer vaccinations as part of their practices, a substantial proportion of pharmacists have not received certification or are not actively involved in vaccinations.

An interest in public health has been associated with seeking immunization certification. Common barriers to providing vaccinations cited by pharmacists include time constraints, lack of available work space, reimbursement issues, and concerns about legal liability.

Among pharmacists who do administer vaccinations, expanding the breadth of vaccines in the pharmacist’s repertoire is an ongoing challenge. Although capable of performing other types of vaccinations (depending on state law), few pharmacist immunizers have moved beyond influenza and pneumococcal vaccine administration.

There are myriad opportunities for vaccinations of children, adolescents, and adults (Table 3, page xx). Pharmacists themselves have expressed a willingness to broaden their practice to include additional vaccines. Areas of significant need include tetanus, diphtheria, and acellular pertussis (Tdap), hepatitis B, and herpes zoster (shingles) vaccines.

In 2010, vaccination coverage rates were 8.2% for Tdap (adults age 19-64 years), 42.0% for hepatitis B (high-risk adults age 19-49 years), and 14.4% for herpes zoster (adults ≥60 years). In an effort to build vaccination service offerings and educational outreach, the APhA, CDC, and other partners are launching a new program called “Pharmacist Prescription to Our Nation’s Immunization Initiative.” Areas of emphasis for this initiative include patients with chronic conditions, vaccine service documentation, and adherence to vaccination recommendations throughout the lifespan of patients.
In general, physicians are willing to collaborate with community vaccinators such as pharmacists to ensure that patients are immunized. Responses to a survey on perceptions regarding pharmacist immunizers indicated that most healthcare professionals believe vaccination administration is an appropriate undertaking for pharmacists.

In a position paper released in 2002, the American College of Physicians and American Society of Internal Medicine declared its support for “the use of the pharmacist as immunization information source, host of immunization sites, and immunizer, as appropriate and allowed by state law.”

Acceptance of pharmacists as vaccinators may be inhibited by a lack of knowledge about their training, experience, or legal authority in this area. Concern also exists that services provided outside the auspices of the patient’s medical home will result in fragmented care with insufficient records transfer. Perceptions can be improved through open exchange of information and collaboration with community prescribers, health departments, and immunization coalitions.

In the early days of vaccine administration by pharmacists, patients questioned the qualifications of a pharmacist to perform vaccinations and expressed discomfort with community pharmacists taking on such a role. Interestingly, these same patients were satisfied with the vaccination they had recently received, not recalling that it had been performed by a pharmacist. In a more recent survey, the vast majority of patients expressed satisfaction with pharmacist counseling and vaccine administration. Conveniency is a key driver of patient preference for receipt of vaccinations in sites other than a physician’s office.

**Education and certification**

The first organized vaccination training program for pharmacists was conducted in 1994. Since that time, more than 175,000 pharmacists have been certified as vaccination providers. Education and certification requirements for pharmacist immunizers vary by state. Some states have developed training programs designed to address their specific needs, whereas others use the APhA Pharmacy-Based Immunization Delivery or equivalent programs.

The majority of pharmacists receive certification through the APHNA course. This program provides not only the practical knowledge needed to perform vaccinations but also the supporting foundational and mechanistic information on vaccines and public health. Upcoming sessions are posted on the APHA website (www.pharmacist.com).

**Immunization education** has become more common in pharmacy schools, but it is not required learning for all students. As of January 2009, roughly 38% of pharmacy schools offered immunization education and training as part of their core curriculum. Other schools may offer immunization courses on an elective basis. The danger of inequalities in education and training lies in the dissemination of information about vaccinations, which may be inconsistent among pharmacists.

### TABLE 3

**2012 RECOMMENDED IMMUNIZATIONS**

<table>
<thead>
<tr>
<th></th>
<th>Children (0–6 years)</th>
<th>Children/teens (7–18 years)</th>
<th>Adults (≥19 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus, diphtheria, acellular pertussis</td>
<td>Orange</td>
<td>Orange</td>
<td>Orange</td>
</tr>
<tr>
<td>Influenza</td>
<td>Orange</td>
<td>Orange</td>
<td>Orange</td>
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<tr>
<td>Inactivated poliovirus</td>
<td>Purple</td>
<td>Purple</td>
<td>Purple</td>
</tr>
<tr>
<td>Varicella</td>
<td>Orange</td>
<td>Orange</td>
<td>Orange</td>
</tr>
<tr>
<td>Measles, mumps, rubella</td>
<td>Purple</td>
<td>Purple</td>
<td>Purple</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Orange</td>
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<tr>
<td>Hepatitis A</td>
<td>Orange</td>
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<tr>
<td>Pneumococcal</td>
<td>Orange</td>
<td>Orange</td>
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<tr>
<td>Rotavirus</td>
<td>Purple</td>
<td>Purple</td>
<td>Purple</td>
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<tr>
<td><em>Haemophilus influenza</em> type b</td>
<td>Orange</td>
<td>Orange</td>
<td>Orange</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Purple</td>
<td>Purple</td>
<td>Purple</td>
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<tr>
<td>Human papillomavirus</td>
<td>Orange</td>
<td>Orange</td>
<td>Orange</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>Orange</td>
<td>Orange</td>
<td>Orange</td>
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</tbody>
</table>

*Recommended for persons age 60 years and older. See vaccination schedules for details of indications and timing for specific vaccinations (http://www.cdc.gov/vaccines/recs/schedules).*

Orange = recommended vaccine; Blue = recommended for catch-up immunization; Purple = recommended if other risk factors are present.
due to differences in knowledge base and experience. Moreover, although the choice to become certified as an immunizer is at the discretion of the pharmacist, in certain cases (e.g., chain pharmacies) it may be a condition of employment.

In addition to immunization education, states may require that pharmacists obtain certification in basic life support or cardiopulmonary resuscitation. All vaccinating pharmacists must undergo Occupational Safety and Health Administration (OSHA) blood-borne pathogen training. OSHA rules dictate that blood-borne pathogen training be renewed each year. Other continuing education obligations are state dependent. It is important that a pharmacist understands the nuances of training and certification to qualify as an immunizer in his or her state. Information on state educational requirements can be found through state pharmacist associations, which are listed on the National Alliance of State Pharmacy Associations website (www.naspa.us).

How pharmacists can improve vaccination rates

Pharmacist-managed programs have been shown to improve vaccination rates among inpatients, clinic attendees, hard-to-reach populations, and the community at large.\textsuperscript{42,45} Taking a step as rudimentary as instituting routine screening can have a profound impact on vaccination coverage. Researchers have shown that regular screening of all patients who attended a secondary prevention lipid clinic resulted in nearly double the percentage of patients who received the influenza vaccine compared with the previous influenza season (Figure 2).\textsuperscript{43} Other interventions that have proven effective for improving vaccination rates include community awareness campaigns, patient reminders, issuing personal health records, computerized record and chart reminders, educating healthcare providers, performance feedback, ensuring vaccine access, home visits, standing order programs, and collaborative practice agreements.\textsuperscript{25,42,44,46} Further information on methods for increasing adult vaccination coverage rates is available through the recommendations and guidelines section of the CDC website (www.cdc.gov/vaccines).

In the hospital setting, simply vetting patients and generating the order for vaccination may not be sufficient to ensure administration. For example, despite increasing the screening rates for influenza and pneumococcal vaccination among inpatients to nearly 100%, the University of Wisconsin Hospital and Clinics had achieved an annual vaccination administration compliance of only 45%.\textsuperscript{47} Using a unit-specific series of interventions involving health unit coordinators, care team leaders, nurses, pharmacy technicians, and pharmacists as well as a host of visual and verbal reminders, the percentage of vaccination compliance increased to 78% the following year. These data highlight the need for coordinated efforts among members of the patient’s care team and follow-up to ensure that vaccination orders are fulfilled prior to patient discharge.

Special populations. The pharmacist may be particularly effective in improving vaccination rates among certain segments of the population, such as those who live in medically underserved areas or who are at significant risk for contracting or suffering complications due to vaccine-preventable infectious diseases.

The paucity of available healthcare resources in rural areas and poor urban areas creates a need for immunization support which pharmacists are well suited to fill. The presence of pharmacies in medically underserved areas makes pharmacists a convenient and accessible source for vaccination education and administration within these communities.\textsuperscript{48}

For some pharmacists, the environment in which they work, such as nursing homes or secondary prevention clinics, brings them in routine contact with high-risk patient populations. In other cases, at-risk patients can be identified through their medication regimens. Medication profiles are routinely accessed as part of the drug utilization review for patients who have submitted prescriptions and could be used to determine comorbidities associated with increased risk.

For example, an insulin prescription would indicate that a patient has diabetes, thus increasing the strength of the recommendation for certain vaccines, such as pneumococcal or hepatitis B vaccines. This type of pharmacoepidemiologic approach to vaccination candidate identification was applied years before the advent of the immunizing pharmacist.\textsuperscript{49}

Screening patients prior to their receipt of a pharmacist-administered vaccination is another method to assess patient risk. This technique was applied by researchers who identified pneumococcal disease risk factors during the screening process for patients receiving an influenza vaccination.\textsuperscript{50} Patients who were determined to be at risk were counseled regarding pneumococcal vaccination. Pneumococcal vaccination coverage rates were significantly higher in cases of pharmacist intervention as compared with benchmark data for traditional care delivery (4.88% vs 2.90%, respectively; $P<0.001$).\textsuperscript{49}
There are many ways in which pharmacists can be active advocates for childhood, adolescent, and adult vaccinations, even among practitioners who themselves do not perform vaccinations (Table 4). Pharmacists continue to play a large role in public awareness of infectious diseases prevention through immunization. Indeed, pharmacies are substantial contributors in terms of dollars spent on public educational and marketing campaigns related to vaccinations.

Efforts in this area might include in-store signage; patient reminders by direct interaction, mailing, or telephone call; stickers or inserts added to prescription bags; use of social media; or special events held in conjunction with National Adult Immunization Week. Perhaps the most significant missed opportunity for building awareness is during direct interactions, such as consultations and prescription fulfillment.

Immunization advocacy need not be limited to individual pharmacy activities; partnering with local organizations and community groups can also expand the pharmacist’s reach. Although convenience is a cornerstone of the pharmacy model for improving vaccination rates, in-pharmacy offerings are not sufficient to address the public need. Bringing vaccination services to such locations as workplaces, churches, schools, and health fairs is a method successfully being used by pharmacists to increase vaccine accessibility.

Travel medicine is another area for vaccination advocacy by pharmacists. Pharmacists running travel health clinics provide advice on prevention of all types of infectious diseases, including vaccination recommendations. A recent comparative study reported that clinical pharmacists who specialize in travel medicine were more likely to recommend vaccines and other medications prior to travel in accordance with guidelines than PCPs who were not travel specialists. Sampling of travel health clinic patrons has demonstrated a high level of patient compliance with pharmacist vaccination recommendations for travel medicine.

The pharmacist’s ability to improve immunization rates is somewhat encumbered by state regulations that limit the scope of vaccination practices. In addition, health plans do not universally recognize pharmacists as immunizers, thus hindering compensation and reimbursement. Pharmacists should be advocates for their own rights and recognition as qualified immunizers by supporting legislation that eases vaccination restrictions and healthcare policies that provide equal coverage to that of other healthcare providers.

**Table 4**

**OPPORTUNITIES FOR PHARMACISTS TO ADVOCATE FOR VACCINATION**

<table>
<thead>
<tr>
<th>Build public awareness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through direct interaction, reminder labels, brochures, posters, bag inserts, mailings, telephone calls, social media, newsletters, seminars, National Adult Immunization Awareness Week</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collaborate with local organizations</th>
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<tbody>
<tr>
<td>Host other healthcare providers, work with immunization coalitions and local health departments, partner with community groups</td>
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<table>
<thead>
<tr>
<th>Extend community outreach</th>
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<tbody>
<tr>
<td>Participate in health fairs, mass immunization clinics, or other programs that bring vaccinations to populations in need</td>
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<table>
<thead>
<tr>
<th>Support policies to achieve consistency in pharmacist roles and recognition</th>
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<tbody>
<tr>
<td>Encourage less restriction on pharmacist-administered vaccinations, recognition by health plans of pharmacists as immunizers, and standardized practices for vaccine claim adjudication</td>
</tr>
</tbody>
</table>

Source: Ref 11,19

**Table 5**

**IMMUNIZATION RESOURCES**

- American Pharmacists Association (www.pharmacist.com)
- American Society of Health-System Pharmacists (www.youcanstoptheflu.com)
- Centers for Disease Control and Prevention (www.cdc.gov/vaccines)
- Vaccine information statements (www.cdc.gov/vaccines/pubs/vis/default.htm)
- List of Immunization information systems (www.cdc.gov/vaccines/progs/IIS)
- Immunization Action Coalition (www.immunize.org)
- Directory of immunization coalitions (www.izcoalitions.org)
- National Alliance of State Pharmacy Associations (www.naspa.us)
- National Foundation for Infectious Diseases (www.adultvaccination.org/professional-resources)
- Society of Teachers of Family Medicine (www.immunizationed.org)
- State health departments (www.cdc.gov/mmwr/international/relres.html)

Resources for pharmacists

A wealth of resources is available, both at the national and local levels, for pharmacists looking to become more involved with immunization education, facilitation, and administration (Table 5).

Through organizations such as APHA, ASHP, CDC, and others, pharmacists can obtain educational materials, locate training classes or continuing education programs, access guidelines, receive vaccine-related updates, download vaccine schedules, research state regulations, gather information on standing orders and protocols, and learn about partnership opportunities.

Partnership within the community, including with local prescribers and health departments, is supported by the APHA guidelines for pharmacy-based immunization advocacy and is a beneficial step for the pharmacist immunizer.
Involvement with local public health departments, immunization coalitions, and other groups not only provides the opportunity for physician collaboration but also allows pharmacists to become involved in policy development and outreach activities.19,24

Local immunization coalitions can be identified through the Immunization Action Coalition (www.izcoalitions.org) or through the state health department (a website listing is available at www.cdc.gov/mmwr/ international/reires.html).

Pharmacists, like all healthcare providers involved in vaccinations, have an ongoing need to stay current with ever-changing immunization recommendations. This information can be gleaned from listservs and e-mail updates (subscription information available at http://www.youcanstoptheflu.com/resources.html), national meetings, continuing education programs, immunization coalitions, and immunization webinars hosted by the APhA (which highlight the outcomes of recent ACIP meetings).

**Conclusion**

Pharmacists perform a vital role in the effort to improve public health through increasing vaccination coverage for common infectious diseases.

Through building public awareness, screening for vaccination needs, hosting other vaccination providers, and becoming certified immunizers, pharmacists can positively influence immunization rates, particularly in medically underserved areas or when rapid healthcare action is needed such as in the case of a pandemic.

Partnership with community organizations, including immunization coalitions, can expand on the access and convenience that draws patients to these nontraditional providers.

References posted online at drugtopics.com.

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**TEST QUESTIONS**

1. Educational and certification requirements for pharmacists to become immunizers are:
   a. Consistent throughout the nation
   b. State-dependent
   c. Dictated by the American Pharmacists Association
   d. Fulfilled by pharmacy school curricula

2. In accordance with individual state regulations, vaccinations can be administered by:
   a. Certified pharmacist immunizers
   b. Pharmacy students, under supervision of a certified pharmacist immunizer
   c. Pharmacy technicians, under supervision of a certified pharmacist immunizer
   d. Both a and b

3. What is the pneumococcal vaccination coverage goal established by Healthy People 2020 for persons 65 years and older?
   a. 60%
   b. 70%
   c. 80%
   d. 90%

4. For whom is seasonal influenza vaccination recommended?
   a. All people age 6 months and older
   b. Patients at high risk due to comorbidities or advanced age
   c. Children younger than age 6 years
   d. Healthcare workers

5. Which of the following is not true of standing orders?
   a. They are endorsed by the American Society of Health-System Pharmacists.
   b. They allow for administration of vaccines without a prescription for patients who meet certain criteria.
   c. They cannot be applied in private practice.
   d. They have been shown to improve vaccination rates.

6. To whom should adverse events that occur in conjunction with a vaccination be reported?
   a. The primary care provider, who will handle further reporting needs
   b. The primary care provider and the Vaccine Adverse Event Reporting System (VAERS)
   c. VAERS and the state health department
   d. FDA and state health department

7. A pharmacy receives a new prescription for an established customer. How might the pharmacist determine whether the patient is considered high risk for a vaccine-preventable infectious disease?
   a. A drug utilization review reveals a prescription profile consistent with a recent myocardial infarction.
   b. The prescription is for an antibiotic.
   c. The patient is receiving multiple concomitant medications.
   d. Patient risk cannot be determined from the information provided.

8. During the 2010-2011 influenza season, U.S. vaccination coverage rates exceeded 51% in:
   a. All 50 states
   b. 47 states
   c. 22 states
   d. 3 states

9. All of the following are barriers to physician administration of the herpes zoster vaccine except:
   a. Medicare Part D coverage makes reimbursement challenging
   b. Shingles is not a significant clinical concern
   c. The vaccine requires frozen storage in a separate sealed compartment
   d. The vaccine is costly to patients

10. As of January 2009, what percentage of pharmacy schools offered immunization education and training as part of their core curriculum?
    a. 38%
    b. 45%
    c. 83%
    d. 100%
CASE A

A health-system pharmacist working in an adult community hospital is approached by administration to develop a plan to increase vaccination rates for its employees and patients. Most of the pharmacists working in this community hospital are not certified to administer immunizations.

1. Which of the following is an appropriate response for a plan to improve rates of vaccination within this hospital?
   a. Increase access by coordinating with other healthcare providers to improve screening and interventions.
   b. No need for pharmacists to be involved, because nurses administer vaccines, and pharmacists are not recognized by most as healthcare providers.
   c. No need for a plan, because current hospital-required initiatives are adequate.
   d. Focus solely on pediatric vaccines to establish herd immunity.

2. Which of the following is not a vaccination-related function of the health-system pharmacist?
   a. Educate patients, families, and healthcare workers about vaccination.
   b. Screen patients at admission or as needed during hospitalization.
   c. Create myths to deter patients from receiving vaccines.
   d. Immunize healthcare workers.

3. Which of the following are required for a pharmacist to become a certified immunizer and administer vaccines?
   a. Maintain active CPR certification and annual OSHA training
   b. Standing orders
   c. Immunization certification course
   d. All of the above

CASE B

A patient with newly diagnosed diabetes arrives at the local community pharmacy with a prescription for its treatment. The student pharmacist who is on rotation with you is counseling the patient on this new prescription. The patient asks the student about vaccinations because the patient’s doctor mentioned that these should be given. The student responds that she is certified to administer vaccines. You, as the pharmacist in charge, are not a certified immunizer. The patient has Medicare Part B and asks to receive the recommended vaccinations.

1. Which of the following is an appropriate action to be taken by the pharmacist?
   a. Let the pharmacy technician vaccinate, to allow the student pharmacist to continue counseling other patients.
   b. Allow the student pharmacist to vaccinate, as she is certified.
   c. Advocate for vaccination and refer the patient to the local health department, where the patient can receive the vaccines.
   d. Explain to the patient that this is really not part of the pharmacist’s responsibility and refer the patient back to the physician.

2. Which of the following vaccinations is covered under Medicare Part B?
   a. Haemophilus influenzae type b
   b. Pneumococcal
   c. Human papillomavirus
   d. Varicella

3. The pharmacist decides to become a certified immunizer. What kind of documentation connected with vaccine administration is necessary?
   a. No need to document unless covered under Medicare Part B.
   b. Report all vaccines administered to the Vaccine Adverse Event Reporting System (VAERS).
   c. Provide vaccine record to the patient and let the patient notify his/her physician.
   d. Report it to the patient’s primary care provider to maintain a medical home.

CASE C

You are a certified immunizing pharmacist working at a local independent pharmacy. You have held numerous health fairs and included vaccinations as part of the screening provided to patients. Your current focus is primarily on influenza and pneumococcal vaccinations, but you are interested in increasing your repertoire of vaccines after attending a seminar describing a new initiative focused on improving vaccination service offerings and educational outreach.

1. The Advisory Committee on Immunization Practices (ACIP) recommends administering seasonal influenza vaccination only to which age group?
   a. Ages 6 months to 18 years
   b. All ages ≥6 months
   c. Age >65 years
   d. Age >50 years

2. Which of the following vaccinations is considered an area of significant need?
   a. Tetanus, diphtheria, and acellular pertussis
   b. Human papillomavirus
   c. Hepatitis A
   d. Varicella

3. With the launching of the new program “Pharmacist Prescription to Our Nation’s Immunization Initiative,” which of the following is not an area of emphasis for this initiative?
   a. Adherence to vaccine recommendations throughout lifespan
   b. Patients with chronic conditions
   c. Vaccine service documentation
   d. Childhood vaccines
NEW DRUG REVIEW Craig I. Coleman, PharmD

**Pancrelipase DR caps approved for EPI**

**Pancrelipase delayed-release capsules**
(Pertzye, Digestive Care, Inc.)

Patients with exocrine pancreatic insufficiency (EPI) cannot digest food properly because they lack digestive enzymes made by the pancreas. On May 18, FDA approved pancrelipase delayed-release capsules to treat EPI resulting from cystic fibrosis or other conditions. Pertzye, a combination of porcine-derived lipases, proteases, and amylases, is the sixth pancrelipase product FDA has approved. It is not interchangeable with other pancrelipase products.

**Efficacy.** The short-term efficacy of Pertzye was evaluated in a randomized, double-blind, placebo-controlled, crossover study of 24 patients with EPI caused by cystic fibrosis. Subjects received an individually titrated dose of Pertzye (≤2,500 lipase units/kg/meal) or matching placebo for 6 to 8 days of treatment, followed by crossover to the alternate treatment for an additional 6 to 8 days. The mean coefficient of fat absorption was 83% with Pertzye compared to 46% with placebo (difference of 36%, 95% CI, 28%–45%; P<.001). The mean change in coefficient of nitrogen absorption also favored Pertzye, compared to placebo (difference of 32%; P<.05).

**Safety.** The short-term safety of Pertzye was assessed in the same crossover study. The most common adverse reactions (occurring in ≥10% of subjects) observed in the clinical trial were diarrhea, dyspepsia, and cough. Delayed- and immediate-release pancreatic enzyme products with the same active ingredient (pancrelipase) have been used for the treatment of patients with EPI due to cystic fibrosis and other conditions. Prior longer-term safety concerns seen with these products include: fibrosing colopathy (a rare adverse event most commonly seen in children or when >2,500 lipase units/kg/meal [or >10,000 lipase units/kg/day] are administered), and hyperuricemia (due to the purines found in porcine-derived pancreatic enzyme products).

**Dosing.** The dosage of Pertzye should be individualized based on clinical symptoms, the degree of steatorrhea present, and fat content of the patient’s diet. It should be initiated at the lowest recommended dose and gradually increased. Specific dosing guidance has been published by the Cystic Fibrosis Foundation. In general, for children >12 months and younger than 4 years of age and weighing ≤16 kg, dosing should begin at 1,000 lipase units/kg of body weight/meal to a maximum of 2,500 lipase units/kg/meal, ≤10,000 lipase units/kg/day, and ≤4,000 lipase units/g fat ingested/day. Adults and children ≥4 years of age and weighing ≥16 kg should begin with 500 lipase units/kg/meal with similar limits. Half of the prescribed dose given for an individual full meal should be taken with each snack. Attempting to divide the capsule contents in small fractions to deliver small doses of lipase is not recommended.

**Taliglucerase alfa**
(Elelyso, Pfizer)

Gaucher disease is a genetic lysosomal storage disease in which a glucosylceramidase deficiency causes lipid to accumulate in white blood cells, spleen, liver, kidneys, lungs, brain, and bone marrow. Type 1 (non-neuropathic) Gaucher disease is most common, occurring in approximately 1:50,000 live births, most often among Ashkenazi Jews. It is characterized by bruising, fatigue, anemia, low blood platelets, and enlargement of the liver and spleen. On May 1, FDA approved taliglucerase alfa, a recombinant active form of the glucocerebrosidase enzyme, for long-term enzyme replacement therapy (ERT) for adults with Type 1 Gaucher disease.

**Efficacy.** Taliglucerase alfa was assessed as part of two 9-month studies of adult Type 1 patients. The first involved 31 ERT-naive patients with enlarged spleens and thrombocytopenia who were randomly assigned to receive either 30 or 60 units/kg/day dosing. Both doses were found effective in reducing spleen volume from baseline. Improvements in liver volume, blood platelet counts, and hemoglobin levels were also observed. In the second study, 25 patients with type 1 Gaucher disease, already receiving imiglucerase (another ERT) for at least 2 years, were switched to taliglucerase alfa at the same dose. The study again showed effective maintenance of the same measures.

**Safety.** Most commonly observed were infusion reactions — occurring in 44%-46% of patients — including headache, chest pain or discomfort, asthma, fatigue, urticaria, erythema, increased blood pressure, back pain, arthralgia, and flushing, and less commonly, angioedema, wheezing, dyspnea, coughing, cyanosis, and hypotension. Such reactions could typically be managed by slowing the infusion rate, pretreating with antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment at a decreased infusion rate. Anaphylaxis was also observed in some patients and is grounds for immediate drug discontinuation.

**Dosing.** Recommended dose is 60 units/kg of body weight administered once every 2 weeks over 60 to 120 minutes; except for patients being switched from a stable dose of imiglucerase, who should receive taliglucerase alfa at the same dose they received imiglucerase. Doses ranged between 11 and 73 units/kg in clinical trials. The initial infusion rate should be 1.3 mL/min, and after patient tolerability to this rate is established, the rate can be increased to 2.3 mL/min. 

Craig I. Coleman is associate professor of Pharmacy Practice, University of Connecticut School of Pharmacy, Storrs, Conn., and director of the Pharmacoeconomics and Outcomes Studies Group, Hartford Hospital.
The Drug Enforcement Administration (DEA) published its interim final rule (IFR) on electronic prescribing for controlled substances (EPCS) more than two years ago. Between that time and now, electronic prescribing networks (such as Surescripts) have worked with both physician and pharmacy application vendors to ensure that EPCS is properly implemented in the spirit of full compliance with DEA requirements.

Requirements for vendors
In order for a physician electronic health record application vendor or pharmacy practice management application vendor to be able to connect its users to an electronic prescribing network, it must first comply with technical requirements set forth by the DEA’s IFR. Thereafter, the vendor must:

- Successfully complete the EPCS certification process, as required by the DEA in §CFR 1311.300 Application Provider Requirements—Third-party Audits or Certifications, and
- Attest to its compliance with all EPCS aspects of 21 CFR § 1300, 1304, 1306, and 1311, in addition to having a written copy of the vendor’s third-party audit or certification.

Upon complying with these requirements, a physician or pharmacy application vendor is permitted to connect its end users by means of an electronic prescribing network for EPCS purposes.

Qualified providers
Several companies are recognized by the DEA in its EPCS IFR as being qualified to perform Part 1311 EPCS audits: SysTrust, WebTrust, SAS 70, and/or certified information system auditors. In addition, the DEA recently specifically approved InfoGuard Laboratories as another company capable of conducting Part 1311 EPCS audits. Other companies may become available as well in the future.

Transactions to date
At present, only a small number of EPCS transactions have been transmitted in those states in which this is currently allowed. Although the DEA has promulgated its IFR, many states still need to align their laws and regulations in order for EPCS transactions to occur.

To date, several physician or pharmacy application vendors have completed the process of becoming certified and audited to connect to an electronic prescribing network for EPCS purposes.

Nationwide deployment of EPCS can only occur once both state and federal laws are aligned in all jurisdictions.

Additional requirements
Vendors are cautioned that in several instances, electronic prescribing networks provide that additional requirements must be met before these pathways can be used to facilitate EPCS. For example, vendors may need to prove that they have completed their Part 1311 EPCS audits as required by the DEA before being activated for EPCS transactions. Additionally, pharmacy directories in prescriber applications are required to indicate which pharmacies are enabled to receive EPCS, and prescribers are able to send EPCS only to those pharmacies, and vice versa.

Finally, in those instances in which an EPCS transaction crosses state lines, both the transmitting prescriber and the receiving pharmacy should be in compliance with both the DEA’s EPCS IFR and the controlled substance laws and regulations of the state in which the prescriber or pharmacy is located.

This article is not intended as legal advice and should not be used as such. When legal questions arise, pharmacists should consult with attorneys familiar with the relevant drug and pharmacy laws.

Ned Milenkovich is a member at McDonald Hopkins, LLC, and chairs its drug and pharmacy practice group. He is also Vice-Chairman of the Illinois State Board of Pharmacy. Contact Ned at 312-642-1480 or at nmilenkovich@mcdonaldhopkins.com.
Summer first aid kit: New items for those stings, bites, cuts, and sprains

DANA K. CASSELL

Sprains, strains, and stings... bruises, burns, and bites can happen year-round, but summer fun seems to bring out the worst in sun, pests, and mishaps. Your patients will be looking for new items for their summer first-aid kits as they set forth, hiking, camping, boating, or simply hanging out in the backyard.

A few options to consider follow.

Wound care

Tec Labs’ recently introduced Tecnu First Aid Gel is a wound-care treatment used to treat minor cuts, scrapes, abrasions, and burns to prevent infection. It is also useful for alleviating the discomfort of bug bites and bee stings that are so prevalent in summer. The gel formulation allows quicker pain relief from the effects of one of its active ingredients, lidocaine. Benzethonium chloride, the other active ingredient, helps prevent a potential infection. Its antibiotic-free formula is a perfect choice for people who are allergic to topical anti-biotic ointments and creams.

Anti-itch

Chattem’s new Cortizone-10 Quick Shot is a 360-degree continuous spray that works at any angle to quickly deliver maximum strength anti-itch hydrocortisone without the mess of creams or ointments. Quick Shot temporarily relieves itching associated with minor skin irritations, inflammation, and rashes resulting from insect bites, poison ivy, eczema, psoriasis, jewelry allergy, and seborrheic dermatitis. The product is easy to use by both adults and children 2 years and older, and it can be used 3 to 4 times daily.

Irritated skin

Summer sweating can increase the unpleasantness that occurs when skin rubs against skin or clothing — leading to exacerbated irritation, chafing, and even bleeding. Chattem has added Friction Defense to its Gold Bond line to help reduce skin friction, as well as to soothe and treat the irritated skin. Friction Defense is a “stick” product that users rub over affected areas as often as needed. It may be applied before irritation (such as before engaging in heated activity or wearing clothing that chafes) as a preventative, or applied to already irritated and sensitive skin to treat and soothe.

Among its ingredients are triglycerides, fumed silica, aloe, ginger root extract, and vitamin E. Unscented and stainfree, this product will be of particular interest to athletes, fitness devotees, uniform wearers, and the obese.

Wraps and braces

Health Enterprises is introducing packaging upgrades for two of its first-aid products — the TheraPOD and the Universal Brace. Eye-catching new colors have been added, and the size of the box has been reduced to better fit retailers’ plansograms. TheraPOD features soothing cool therapy and natural moist heat using long-grain rice. The Universal Brace will...
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First aid
Continued from pg. 40

soon feature a clear package allowing the consumer a better view of the product. The brace features Hot and Cold Therapy, as well as support for an ankle, knee, or elbow. Health Enterprises is also introducing a new item, the UltraWrap — a 2.5” x 48” athletic wrap used to provide superior compression and support. The patented technology, used for years by physicians, trainers, and physical therapists, now will be available to retail.

The UltraWrap provides 10 or more uses compared to the average 2 uses for other wraps. Its 4-way stretch allows for effective wrapping around skin; it then returns to its original state after use. The large size allows the user to wrap it to the desired level of support. Its 2.5-inch width differentiates the UltraWrap from other products on the market, which are sold in 2”, 3”, and 4” sizes. The wrap is breathable, wicks away perspiration, stays securely in place, and is latex-free.

Bandage innovation
Tender Corporation has launched an innovative bandage solution under its Easy Care First Aid brand. Created for people on the go, the Easy Access Bandage comes in a convenient portable paper pack. The architecture of the pack creates a fan of bandages, enabling the user to pull the top of the wrapper only slightly to release a sterile bandage that is ready for application with one hand. There is only one bandage tab to dispose of; the rest remains attached to the portable structure, eliminating loose bandages and paper wrapper waste. A pack of 30 fabric bandages, 1”x3”, retails for $2.97.

New look
Earlier this year, Tender Corporation set out on a package redesign, with the goal of enhancing the position of After Burn as a healing brand. After Burn products offer maximum strength pain relief (active ingredient is 2.5% lidocaine) in easy-to-use formulas that promote healthy skin. The redesigned box, in a simple bright blue, retains the brand’s familiar red-on-white label and is meant to catch the eye on a shelf full of “busier” packaging.

Seat relief
A hemorrhoid can interfere with almost everything one does. To help address this problem, which affects especially millions of Americans between the ages of 20 and 50, Ferndale Healthcare has launched RectiCare Anorectal Cream, a topical over-the-counter local anesthetic, containing the strongest nonprescription lidocaine available (5%). RectiCare Cream works very quickly to relieve pain, itching and burning associated with hemorrhoids and other anorectal disorders. A supply of “finger cots,” little covers that fit over the finger, is included with each tube to promote hygienic application, since the finger (skin) doesn’t come into contact with the product or the area to which it’s being applied.

Although not everyone who has a hemorrhoid has an attendant problem requiring pain management, patients with discomfort will be pleased to know that an OTC product will be readily available at drugstores without a prescription. (www.recticare.com / www.ferndalehealthcare.com)

Dana K. Cassell, a frequent contributor to Drug Topics, lives in North Stratford, N.H.

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Corporate Greenstone 29s
Corporate Roxane Laboratories 21s
Corporate United Drugs 41
Corporate Teva Pharmaceuticals USA Supp CV2
Corporate Live Oak Bank CV3
Corporate Mylan Pharmaceuticals Inc. CV4, 23s
Corporate Ascend Laboratories LLC 39s
Corporate Cambier Pharmaceuticals Inc. 37s
Corporate Greenstone LLC 29s
Corporate Kremers Urban Pharmaceuticals 33s
Corporate Winthrop Supp C4
I-Caps Alcon 7
Label EPS Inc. 21
Lice Shield Lorrainead 9
Phillips’ Colon Health Bayer Healthcare LLC 13
Rid Bayer Healthcare LLC 25a
**RX & OTC**

**New products**

- **Belviq** (lorcaserin hydrochloride) has been approved by FDA for the management of weight reduction in adult patients with an initial body mass index (BMI) of 30 kg/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes). This drug is intended for use in conjunction with a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 kg/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes). FDA has recommended that the U.S. Drug Enforcement Administration (DEA) classify Belviq as a scheduled drug. After DEA determines the final designation, Eisai will announce U.S. availability. Arena will manufacture and supply the commercial product from its Swiss facility and Eisai will handle U.S. marketing and distribution. ([www.arenapharm.com](http://www.arenapharm.com) / 858-453-7200)

- **MenHibrix** (Meningococcal Groups C and Y and Haemophilus b [hib] tetanus toxoid conjugate vaccine) has been approved by FDA for the infant immunization schedule for Hib vaccination and to allow for vaccination against meningococcal groups C and Y without adding additional shots. GSK will provide additional details on MenHibrix availability in the near future. ([www.gsk.com](http://www.gsk.com) / 888-593-5977)

- **Perjeta** (pertuzumab), a new anti-HER2 therapy to treat patients with HER2-positive late-stage (metastatic) breast cancer, has received FDA approval. Perjeta is combined with trastuzumab, another anti-HER2 therapy, and docetaxel. It is intended for patients who have not received previous treatment for metastatic breast cancer with an anti-HER2 therapy or chemotherapy. HER2 is a protein involved in normal cell growth. It is found in increased amounts on some types of cancer cells (HER2-positive), including some breast cancers. Perjeta is administered intravenously and is believed to work by targeting a different part of the HER-protein than trastuzumab, resulting in further reduction in growth and survival of HER2-positive breast cancer cells. ([www.perjeta.com](http://www.perjeta.com) / 888-249-4918)

- **UCB** has launched Neupro (rotigotine transdermal system) in the United States. Approved by FDA in April to treat the signs and symptoms of early and advanced idiopathic Parkinson’s disease and moderate-to-severe primary Restless Legs Syndrome (RLS), Neupro, a once-daily patch that provides continuous delivery of the dopamine agonist rotigotine for 24 hours, is now available in U.S. retail pharmacies. Neupro should be stored in a refrigerator. There is no need for patients to transport these patches in special containers and they must not be stored in a freezer compartment. ([www.neupro.com](http://www.neupro.com))

**New formulation**

Lupin Pharmaceuticals has received FDA approval for **Suprax** (Cefixime) 400-mg antibiotic capsules, which is a new dosage. The approval will expand Lupin’s range of Suprax dosage forms available to treat the approved indications in appropriate patients. Product is available in 100 mg/5mL and 200 mg/5mL suspension, as well as 400-mg tablets. Lupin expects to commence shipping the product in the near future. ([www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com) / 866-587-4617)

**New indication**

FDA has approved Baxter’s **Gammagard Liquid 10%** (immune globulin infusion [human]) as a treatment for multifocal motor neuropathy (MMN). This is the first immunoglobulin treatment approved for patients with MMN in the U.S. MMN is associated with a progressive, asymmetric limb weakness mostly affecting the upper limbs, which can lead to significant difficulty with simple manual tasks. This indication has been granted U.S. orphan drug designation, as the prevalence of MMN is estimated at between one and two persons for approximately 100,000 individuals. ([www.baxter.com](http://www.baxter.com) / 800-422-9837)

GSK and XenoPort announced that **Horizant** (gabapentin enacarbil) **Extended-Release Tablets** for the management of adult postherpetic neuralgia (PHN), pain associated with shingles. The drug was originally approved by FDA to treat adults with moderate-to-severe primary restless legs syndrome. Recommended dosage for the management of PHN in adults is 600 mg twice daily. Treatment should be initiated at a dose of 600 mg in the morning for three days followed by 600 mg...
twice daily (1,200 mg/day) beginning on day four. Doses must be adjusted in patients with impaired renal function. (www.horizant.com / 888-825-5249)

FDA has approved the use of Pfizer’s Lyrica (pregabalin) capsules CV for the management of neuropathic pain associated with spinal cord injury. Lyrica received a priority review designation for this new indication from FDA. More than 100,000 patients, approximately 40% of the 270,000 patients with spinal cord injury in the United States, suffer from this chronic, complex pain condition. Neuropathic pain associated with spinal cord injury can be severely debilitating and may significantly hinder rehabilitation and the ability to regain function. (www.lyrica.com / 800-879-3477)

New generics
Dr. Reddy’s Laboratories has launched ropinirole hydrochloride XR (Extended-Release) tablets (2 mg, 4 mg, 6 mg, 8 mg, and 12 mg), a bioequivalent generic version of GSK’S RequipXL tablets, in the U.S. market, to treat Parkinson’s, following FDA approval of the company’s abbreviated new drug application. (www.drreddys.com / +91-40-49002900)

Teva has announced the launch of olanzapine and fluoxetine capsules USP 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg, and 12 mg/50 mg, the generic equivalent of Symbyax. Symbyax, marketed by Lilly USA, is approved for the acute treatment of treatment-resistant depression and bipolar 1 depression in adults. (www.tevapharm.com / +972-3-9267267)

ActAVIS has received FDA approval to market mixed amphetamine salts ER capsules (dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules CII), in all available strengths: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg. The product is the generic version of Shire’s Adderall XR CII. Distribution of the product has commenced. (www.actavis.com / +41 (0)41 462 7300)

Perrigo has received final FDA approval for its abbreviated new drug application for clindamycin phosphate and benzoyl peroxide 1.2%/5% topical gel [1], generic for Stiefel Laboratories’ Duac Gel, indicated for the topical treatment of inflammatory acne vulgaris. Perrigo has commenced shipment of the product. (www.perrigo.com / 269 673-8451)

Teva UK has launched lbandronic acid 150-mg film-coated tablets for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. The product is a generic version of Boniva from Roche. (www.teva.uk.com / 0207 540 7117)

OTC
Conazol, an over-the-counter athlete’s foot treatment manufactured in Mexico by Liomont Laboratories, is now available in the United States in a 30-g tube. The brand can be found at such retailers as Walmart and Target in key Hispanic markets, including Los Angeles, Houston, Dallas, and Chicago. Containing miconazole nitrate 2% antifungal, Conazol provides consumers the maximum strength formulation available without a prescription to cure and prevent most cases of athlete’s foot. Conazol is imported exclusively by MarcasUSA LLC. (www.MarcasUSA.com / 800-428-9489)

Biolife has launched WoundSeal Powder, a hemostat product specifically for individuals on a regimen of blood thinners. While hemostat products have been introduced before, WoundSeal is said to be the first one to target patients on specific therapies. WoundSeal is a topical powder that allows consumers to take control of bleeding cuts and nosebleeds. Its powder technology combines a hydrophilic polymer and potassium ferrate to stop bleeding in seconds by creating an instant scab (or seal) when combined with the wound’s own blood. The instant scab seals the wound, which stops the bleeding, and helps prevent infection by creating a microbial barrier over and around the wound. WoundSeal is available for purchase at all Walgreens stores and online. (www.woundseal.com / 800-722-7559)

From Sebamed USA, come a pair of botanically based hair-care products that moisturize the scalp, preserve natural oils, and maintain the natural structure of the hair. Sebamed Everyday Shampoo is a soap-free lathering shampoo that protects the natural acid balance of hair and scalp without stripping away natural oils. It is formulated to treat normal, sensitive, and problematic scalp conditions. Sebamed Repair Conditioner is developed to moisturize hair and scalp with vitamin B5, avocado oil, and plant extracts to naturally strengthen hair. It is 100% soap-, alkali-, and paraben-free, and is appropriate for all hair types. Products are available at Costco, CVS, and online at sebamedusa.com. (www.sebamedusa.com)

New device
SHL Telemedicine Ltd., a provider and developer of advanced personal telemedicine solutions, has received FDA approval for the marketing of the Smartheart [2] mobile health device. Through technology developed by SHL, the Smartheart will enable anyone who owns a smart phone (iPhone, Android, and Blackberry) to perform a hospital-grade ECG. The Smartheart enables the user to send the ECG results in real time to the company’s telemedicine call center or his personal physician or cardiologist, to upload the results to his personal medical record, or to send them to the hospital for medical diagnosis. The ECG results can be viewed and examined on the smart phone by anyone, anytime, anywhere, through secure access. (www.getsmartheart.com / +972(3)561-2212)
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I couldn’t resist. I touched her arm lightly when I asked how I could help her. I think that she liked that. Her eyes twinkled as she smiled at me. “My memory,” she said, “It’s foggy.”

“What are you taking?”

“I’m not loaded,” she said. “I haven’t smoked up in 20 years.”

“No, I meant prescription drugs.” It’s true that plenty of people who smoked dope when they were 20-somethings in the 1960s are still doing it in 2012. When I counsel older patients on their prescription drugs, however, I rarely consider that they may be using recreational drugs.

“I do not take prescriptions. I want only natural herbs. My friend told me that something called Gingle could help with my fog problem.”

“Ginkgo,” I said. “It’s supposed to help with memory. At least that’s what Varro Tyler claimed, and he was the most famous pharmacognosy expert of modern times.”

“I had to explain what pharmacognosy is.

“It’s natural?”

“Yes, it is natural.”

“Good, I want a bottle.” She looked at me. “It will be okay with my A-fib?”

Hang on, Sloopy. “Are you taking a blood-thinner?”

“Just a tiny pill. It’s natural. I don’t take drugs.”

“I don’t think you want to take ginkgo,” I said. “It can cause bleeding, and you’re already on a blood thinner.”

“But why? If it’s just an herb, how can it cause bleeding?”

“I don’t know how it causes bleeding. It’s in Varro Tyler’s book, and we can trust him. No ginkgo for you. I’m sorry.”

Whooping cough is also natural

Recently, a young mother asked me what she could get for her toddler to prevent whooping cough. She was taking her son to visit her sister in western Washington State, where there is a pertussis epidemic. Mount Vernon, Washington is a magnet for back-to-nature types. Herd immunity has broken down.

“I’m guessing that your child hasn’t had any of his shots.”

“Shots aren’t natural,” she said. She crossed her arms across her chest, expecting an argument.

“Whooping cough is natural,” I said. “Nature is cruel, unforgiving, and deadly. You probably should put off your trip to see your sister until after you’ve gotten your son caught up on his shots.”

“I have to go. It’s her birthday.”

“I sighed. “Nature is arbitrary and heartless. Nature doesn’t care if your son hasn’t had his immunizations. Nature just kills.” It has always been my style to tell the unvarnished truth.

“histoire?”

“Why don’t you use the real Viagra?”

“That’s what my doctor said.”

“Well, why not?”

He told his story then. His new girlfriend was an old hippie from Austin. She was against allopathic remedies. “If I used the real Viagra, she wouldn’t do it then. She wouldn’t let me stay the night.”

This was very strange. Perhaps she just didn’t want to go to bed with an old guy pretending to be Broadway Joe.

“I like that Seal idea. I’ll just tell her that I am cured naturally.”

Jim Plagakis is a community pharmacist in Galveston, Texas. You can e-mail him at jplagakis@hotmail.com and cc us at drugtopics@advanstar.com. You can also check out his website at jimplagakis.com.
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