The Changing Role of OTC Products in Health Care
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This activity has been developed for nurses whose practice calls upon them to assist and counsel patients who may benefit from using over-the-counter products as part of a self-directed healthcare regimen. The role of generic OTC and store-brand products are reviewed, as well as the ongoing trend of medications switching from prescription-only to OTC status. Despite their perceived safety, OTC products can be associated with adverse effects. Important updates on the safe use of OTC products for peptic ulcer disease, allergies, birth control, pain management, and overactive bladder are also discussed.

Learning Objectives

The target audience for this activity is nurses.
At the completion of this activity, the participant will be able to:

- Describe the evolving patient attitudes toward healthcare and wellness, specifically in the context of OTC medications
- List the products that have moved from prescription-only to OTC status
- Describe the most common medication problems with specific OTC medications
- Identify the economic implications of brand, generic, and store brand products

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Accreditation

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This activity provides 1.0 contact hour of nurse CE credit.

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About the Faculty

Rachel Caskey, MD

Rachel Caskey, MD, MAPP, is an Assistant Professor of Internal Medicine and Pediatrics at the University of Illinois at Chicago (UIC). She is board certified in both pediatrics and internal medicine and is a primary care provider for all ages. Dr. Caskey is a health services researcher, whose research interests include improving adolescent vaccination efforts through examining barriers to vaccine adoption, transitions of care for children who age-out of the pediatric healthcare setting, and exploring ways to modify preventive health behaviors among young adults. Dr. Caskey has an appointment at UIC’s School of Public Health, Division of Maternal and Child Health, and is a member of the UIC Cancer Center, where she collaborates on efforts to examine the use of the HPV vaccine to reduce the incidence of cervical cancer.

Patricia Fischer, RN, CCRP

After a 15-year career as an intensive care nurse, Pat Fischer came to the University of Illinois at Chicago (UIC) in 1990 to serve as a Clinical Research Coordinator for the Epilepsy Clinical Trials Program, a collaborative research program that has performed over 30 clinical trials evaluating 9 antiepileptic drugs during her tenure. Since 2007, her responsibilities have included the Quality Improvement Program in the Office of the Vice Chancellor for Research and the UIC IRB Expedited Review team. She is a member of the Society of Clinical Research Associates, with whom she has earned certification as a clinical research professional. In addition to teaching at the UIC Colleges of Pharmacy and Nursing, Pat has presented regional and national lectures on nursing aspects of epilepsy care and clinical practice guidelines.

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Mary Lynn Moody, BSPharm, is a Clinical Associate Professor in the Department of Pharmacy Practice at the University of Illinois at Chicago College of Pharmacy. She is also the Director of Business Development for the Drug Information Group. In this role, she is responsible for development and coordination of business relationships with clients of the Drug Information Group. Mary Lynn completed her pharmacy degree at the University of Illinois at Chicago and a PGY1 residency at Northwestern Memorial Hospital in Chicago.

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Jim Wisner is President of the Wisner Marketing Group in Libertyville, Ill. He launched his company in 1999 after accruing over 30 years of senior management experience in the food and drug industry at Jewel Food Stores, Shaw's Super-markets, and Topco Associates, where he was responsible for the OTC product area and launched the Topco Pharmacy Program. He has developed several industry-wide research and education programs in consumer healthcare and other topics. Jim has contributed to numerous pharmacy education activities, focusing on self-care and patient behavior in the community pharmacy setting. Jim received his BBA in Marketing from the University of Notre Dame and his MBA from the Kellogg Graduate School of Management at Northwestern University. He previously held a visiting position at the University of Illinois at Chicago College of Pharmacy.

Disclosures

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So, what is this CE activity really all about? Why do we want to focus on OTC products and store brands?

Why are we discussing OTC drugs? Physicians do not prescribe these products. Should they be concerned about self-care? Should nurses have an interest in the OTC products that patients use?

The fact is, self-care really is healthcare today. 88% of consumers surveyed stated that they would go to the physician’s office less frequently if they could use OTC drugs.
Almost all Americans (87%) believe that OTCs are safe when taken as directed.

For women it is “prime time.” Each day, 6,000 women reach menopause. In a well-known study, women indicated that, aside from personal illness, nothing impacts how they manage their health and well-being more than the onset of menopause. It is also worth noting that women are the drivers of most family healthcare decisions.

Today, self-care is health care. A number of factors drive this trend:

Aging baby boomers account for a significant proportion of the population, and they will become even more in need of healthcare as they age.

Patients today have access to more information about self-care treatment and what to do than they ever have in the past. 20 years ago patients didn’t have any of the hundreds of Internet sites and sources of information to help them assess their ailments and acquire an understanding of what products may be appropriate to deal with them.

Many new products on the market offer new ways to treat a wide range of health conditions.

Most significantly, many popular Rx drugs are evolving to OTC status.
The last of the baby boomers turn 50 years old in 2014. It is important to understand that “over 50” is really not “over the hill” – it is the hill that is driving healthcare today.

Individuals over 50 account for 70% of all prescription drug purchases and more than half of all OTC purchases. One-third of all OTC purchases are made by those over the age of 65. That group will continue to grow in the future as well. Equally important, personal healthcare expenditures begin to increase dramatically at age 45, nearly tripling before most individuals reach retirement age.

In recent years, direct-to-consumer advertising of prescription drugs has increased. And with the many Rx-to-OTC launches, more healthcare communications and advertising have been targeted to consumers than ever before. Many other channels, such as ongoing media coverage and popular literature, provide even more information. Just take a look at how many magazines – and now even mobile apps – are dedicated to or directed at health and wellness topics.

Over 80% of Internet users today look for health and medical information online. Most everyone looks for that information before making a visit to the doctor, and in many cases they feel that they may be as well – or perhaps even better– informed than the doctor when they arrive.
OTC is important. 35% of all adults in the United States use OTC medications on a regular basis. U.S. consumers make an average of 26 trips per year to purchase OTC products, but only 3 trips per year to the doctor’s office.

Physicians agree about the positive benefits accrued when patients first turn to OTC medications to self-manage minor ailments. 89% of doctors surveyed believe responsible OTC use would ease the patient-care burden on medical professionals. 76% of physicians agree that having OTC medications available helps make managing patient health easier. Physicians also estimate that an average of 10% of office visits would be reduced with self-managed OTC use.

OTC medications are the first choice of most people to treat minor injuries or ailments. To illustrate this, 81% use OTC products, while only 27% will schedule a doctor appointment.
Nearly all consumers believe that OTC medicines make it easy to treat minor medical ailments and prefer to treat themselves before seeking professional care. 86% of OTC users believe these products make doctor visits unnecessary. 85% of parents even prefer to treat their children with an OTC product first – before visiting the doctor.

Consumers support the use of OTC products because they are cost-effective. They save $102 billion annually relative to alternatives such as doctor visits and prescription drugs. On average, every dollar spent by consumers on OTC medications saves the U.S. healthcare system $6 to $7. In an age where the cost of healthcare is constantly under discussion, OTC medications are probably one of the most immediate and effective ways to rein in healthcare costs.

This is an example of what happens when a drug is switched from prescription status to OTC, and then eventually makes its way to store brand or generic alternative. When Prilosec was originally a prescription drug, it cost patients nearly $1,500 per year to maintain their regimen. When the generic prescription form was introduced, the cost was cut by more than half. Moving to OTC, the branded product again cut the price in half. And, since it could be purchased on sale or at a discounted price, most individuals were able to buy it at about one-third the cost of the generic prescription drug. When Omeprazole became a store brand, the cost again was nearly halved. Ultimately, the patient moved from a medication regimen that cost nearly $1,500 per year to maintaining the same drug regimen for a little over $100 a year.
The federal government’s multiple changes in flexible spending accounts have been very confusing for many people. Until 2002, patients paid the full cost of OTC products. In 2003, these products were made reimbursable through flexible health spending accounts. In 2011, as part of the Patient Protection and Affordable Care Act, OTC products were not reimbursable without a written prescription. This change has far-reaching repercussions for patients and the healthcare system. Some of your patients may ask for prescriptions for OTC medications in order to obtain reimbursement for them.

Store brands are the OTC equivalent to generic Rx drugs. Their ingredients compare with those of the top-selling national brands, and the packaging often helps patients identify the national brand equivalent. Store brands are most often sold under a particular store’s name or label (or a name or label that they control) and sometimes are referred to by pharmacists as “generic OTC.”

Store brands, also referred to as “private label” – dominate most OTC categories in which they are sold. Private label analgesics far outsell the leading brands, and collectively outsell the next 9 brands combined. A recent University of Chicago study also found that pharmacists choose store brands for themselves 90% of the time.
In unit sales, the store brand share is even higher. Across the board, these products have become the leading choice for most consumers, and they now collectively represent over 46% of total unit sales across all channels. When reassessed on a volume basis (the same as equivalent doses), store brands represent 59% of all OTCs taken.

In terms of quality, are store brands different from their advertised brand counterparts?

The most important thing to understand about store brands is that they must adhere to the exact same standards as advertised brands.

Both store brand and advertised brand manufacturers are held to the same FDA standards and requirements for safety and common good manufacturing practices (cGMPs).

All generic and store brand manufacturers must commit to the same manufacturing best practices, or cGMPs. They are reviewed, audited, and controlled by the FDA to the same extent as all other manufacturers. These manufacturing best practices extend all the way from in-bound materials to the shelf.
Which categories are growing? Private-label analgesics, probiotics, and glucosamine are all areas of growth.

Rx-to-OTC switches are estimated to be $44 billion during the 5-year period between 2010 and 2015. Nearly two-thirds of all Americans wish that at least some of the prescription medications they currently take would be made available over the counter. OTC is accessible, convenient, and can often preclude the need to see a doctor.

Switch activity is likely to increase. Although there was a hiatus after some issues related to Cox-2 inhibitors a few years ago, the FDA is again becoming proactive in moving drugs to OTC status. There are some very good reasons for this. Among the top 15 industrialized nations, life expectancy in the United States ranks last. One explanation is that all of the other nations have a much greater focus and reliance on self-care than is typical in the U.S., and most of these countries have been more aggressive in moving products to OTC status. The FDA believes that drugs that can be safely taken and managed by patients should be made available as OTC products.
This list includes some of the drugs currently being reviewed for future switches. The list is fluid and changes as the FDA assesses new information.

The possibility of statins moving to OTC status provides a good example of how Rx-to-OTC switches will continue to have an impact. Mevacor is already OTC in the United Kingdom.

The FDA has several specific requirements to be met before a drug can be switched to OTC status. The benefits must outweigh the risks when it is used as an OTC as opposed to a prescription product. Also, there must be little potential for misuse and a low likelihood of abuse. Consumers should be able to recognize the medical conditions for which the product is used and capable of self-treating and using the drugs correctly. Finally, the drug must be adequately labeled for use in a way that is clear and understandable.

Rx-to-OTC conversions take time – they can be very costly. Generally, both use and label comprehension studies are required before the drugs are approved. Product safety issues are handled on a case-by-case basis.

On the other hand, there are some potential pitfalls when combining OTC drugs with prescription medication. In one study, 25% to 75% of patients taking oral chemotherapy were also taking OTC drugs that decreased the effectiveness or increased the side effects of the cancer treatment.

Many people feel that a product must be safe if it is available over the counter, and do not consider potential drug-drug interactions.

When moving from traditional OTC drugs to nutraceuticals such as St. John’s wort or saw palmetto, there are even more potential risks.
Here are some key points about OTC medications that the clinician should review with patients.

Proton pump inhibitors (PPIs) are the third highest-selling class of drugs in the United States, with more than 100 million prescriptions and $13.9 billion in prescription drug sales in 2010. With widespread and frequent long-term use of PPIs, some serious adverse effects have been identified, suggesting a need for more selective prescribing practices. This is particularly important for older adults who may be more vulnerable to these adverse effects. There is increasing evidence that PPI therapy may be associated with the development of Clostridium difficile infections and hip fractures.

PPIs are beneficial when used appropriately; however, they are often overused and misused. There are reports of PPIs being initiated or continued for prolonged periods of time, without sufficient evidence to support their use. In one study, more than half of elderly patients who were prescribed PPIs at discharge had no documented indication for treatment. A second study showed that 65% of inpatients who were given PPIs did not have an approved indication for their use. Some examples of unapproved use of PPIs – without evidence to support their use – include treatment of low-risk patients as prophylaxis against “stress” ulcers and concurrent administration with corticosteroids to prevent peptic ulcer disease in non-critically ill patients.
PPIs and C. difficile–Associated Diarrhea

- FDA warning to prescribers in February 2012
- Increased risk of C. difficile–associated diarrhea (CDAD)
- Diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve
- Established risk factors for CDAD include residence in a nursing home and advanced age
- Gastric acid has a protective role against ingested bacteria
  - Decreasing acid with PPI use may facilitate colonization by C. difficile with subsequent toxin production and toxin-mediated intestinal injury and inflammation

The FDA issued a warning to prescribers in 2012 regarding the use of PPIs and an increased risk of C. difficile–associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve. CDAD is the most commonly diagnosed institutional-acquired diarrhea, with an incidence of 0.1-2% in hospitalized patients. Residence in a nursing home and advanced age are two established risk factors for CDAD. Studies suggest that acid-suppressive therapy is also a risk factor. Gastric acid has a protective role against ingested bacteria. Decreasing acid with a PPI may facilitate colonization by C. difficile with subsequent toxin production and toxin-mediated intestinal injury and inflammation.

PPIs and Hip Fractures

- May 2010: FDA released safety update on use of PPIs and risk of fracture
  - Based on several epidemiologic studies that reported increased risk of fractures of the hip, wrist, and spine with PPI use
  - Greatest risk: high doses of PPI or use >1 year
  - Most studies were in individuals over the age of 50 years

In 2010 the FDA released a safety update on the use of PPIs and the risk of fracture. The new safety information is based on FDA review of several epidemiologic studies that reported an increased risk of fractures of the hip, wrist, and spine with PPI use. Some studies found that those at greatest risk for these fractures received high doses of PPIs or used them for 1 year or longer. The majority of the studies evaluated individuals 50 years of age or older, and the increased risk of fracture was observed primarily in this age group.

Discussion Points for Physicians

- Identify patients who are taking OTC PPIs for >1 year and discuss risks with them
- Consider alternative products, including H-2 blockers

Physicians should identify patients who are taking PPIs for longer than 1 year and discuss the risks of fracture with them.
Patients should be counseled on the need to avoid foods that trigger heartburn or other symptoms. In addition, the nurse should encourage any overweight patients to lose weight to reduce the risk of symptoms.

Nasacort 24HR is the first OTC intranasal corticosteroid available in the U.S. It is approved for treatment of allergic rhinitis. Allergic rhinitis occurs when patients present with 2 or more symptoms, such as nasal congestion, rhinorrhea, sneezing, or itchy nose, eyes, and throat.

Current guidelines recommend treatment based on the severity of symptoms and how long the patient has suffered with allergic rhinitis. If persistent (i.e., symptoms for >4 days per week and for >4 weeks per year) and if symptoms are moderate to severe, the choice would be an intranasal corticosteroid.
Nasacort is approved for use in children >2 years and adults. The adult dose is 1-2 sprays in each nostril once a day, while children aged 2-12 years should receive only 1 spray in each nostril once a day.

The most common adverse effects of Nasacort include headache, nasal irritation, pharyngitis, and nosebleeds. Children taking Nasacort for extended periods may be at risk for growth suppression.

Here are some key points about intranasal corticosteroids that the clinician should review with patients.
Although acetaminophen has been on the market for decades, overdoses with acetaminophen still account for 55,000 to 80,000 emergency room visits each year. At least 500 patients die each year from acetaminophen overdose. Nearly 1 out of every 4 adults in the U.S. uses acetaminophen weekly, and it is found in more than 600 prescription and OTC products.

In 2011, the FDA changed the product labeling for acetaminophen to reduce the total daily dose to 3,000 mg, or 6 extra-strength tablets. The manufacturer of Tylenol has also added new warning labels on the caps of their Tylenol products to remind consumers that they contain acetaminophen.

In 2013, the FDA released a new warning regarding acetaminophen. There have been reports of severe skin reactions, including reddening of the skin, blisters, and rash. These skin reactions (Stevens-Johnson Syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis) can occur with the first dose or with longer-term use. These reactions can also be fatal.

The risk of liver damage with acetaminophen continues to be a significant problem and physicians should discuss this with patients. Physicians need to be aware of the risk of skin reactions with acetaminophen and communicate that risk with the patient. Patients should be instructed to stop acetaminophen if they develop a rash, and to contact their physician.
Plan B One Step contains 1.5 mg of levonorgestrel, taken as a single dose. It should be taken as soon as possible after unprotected intercourse, and may reduce the risk of pregnancy if taken within 72 hours of unprotected sex.

It is designed to be used after a normal contraceptive method fails, is not used, or is not available – not for routine use. This product is not an abortifacient.

Plan B One Step was approved in 2006 for non-prescription sale to women over 18 years of age. In June 2013, it was made available as an OTC product without age restrictions. The store brand formulation is expected in 2014.

It is important to be aware of potential drug interactions with emergency contraception. CYP3A4 inducers, such as barbiturates, carbamazepine, felbamate, phenytoin, rifampin, and St. John’s wort, can reduce the effectiveness of emergency contraception. Drugs used in the treatment of HIV can also impact the effectiveness of emergency contraception.
Ask female patients about EC – are they aware of it? Have they used it? Be sure to discuss the fact that EC does not protect the patient against sexually transmitted diseases.

Gauge the patient’s knowledge about EC, and whether they have ever used it. Reinforce that EC is not intended to be used for routine birth control. In some patients, the nurse may want to discuss the benefit of having a supply of EC on hand in the home for emergency use.

Oxytrol is indicated for overactive bladder and has been available by Rx for a number of years. Studies have shown that women can understand the label and how to use this medication. It approved for use in women over 18 years of age.
The patch is applied once every 4 days to the abdomen, hip, or buttocks. The application site should be rotated to prevent rash and itching.

There are several contraindications to the use of oxybutynin, including uncontrolled narrow-angle glaucoma, urinary retention, and gastric motility disorders. This medication should not be used in patients with dementia. Anticholinergic side effects can include hallucinations, agitation, confusion, and somnolence.

Patients taking Oxytrol should not take other anticholinergic agents. They should also avoid combing Oxytrol withazole antifungals or macrolide antibiotics, since these anti-infectives can increase the risk of oxybutynin toxicity.
Other conditions associated with frequent urination include urinary tract infection, diabetes, and pregnancy. These conditions should be ruled out before advising the patient to use Oxytrol for overactive bladder.

Physicians should ask women with urinary symptoms if they are using OTC drugs to control their condition. Be sure to discuss potential drug interactions and side effects with the patient.

Nurses plan an important role in reviewing the need for medication adherence. It is important to remind patients that Oxytrol is only to be used for overactive bladder.
Physicians and nurses are in a unique position to have an impact on OTC medication use. They can reassure patients about the safety of OTC products, including the store-brand products. Clinicians should encourage high-risk patients to talk with their pharmacist before using OTC drugs. High-risk populations include those with comorbid conditions, the elderly, pregnant patients, and children.

Summary

- Physicians and nurses are in a unique position to influence OTC medication use.
- Can reassure patients regarding OTC safety.
- Encourage consult with the pharmacist before using OTC drugs, especially in high-risk populations:
  - Those with comorbid conditions
  - Elderly
  - Pregnancy
  - Children
Post-Test

1. What percentage of adults in the U.S. uses OTC medications on a regular basis?
   A. 10%
   B. 35%
   C. 50%
   D. 65%

2. For every dollar spent on OTC medicines, how much is saved by the U.S. healthcare system?
   A. $2 – $3
   B. $4 – $6
   C. $6 – $7
   D. $10 – $11

3. The FDA has specific requirement for switching a drug from Rx to OTC, including:
   A. Benefits must outweigh the risks
   B. Low risk of abuse
   C. Product can be adequately labeled for use
   D. All of the above

4. Individuals over the age of 50 account for what percentage of OTC purchases?
   A. >50%
   B. <60%
   C. >40%
   D. <40%

5. A 63-year-old female patient is at your office for her annual check-up. While discussing her overall health, she explains that she has been having “problems controlling her urine.” She says that she has to urinate 2 or 3 times during the night, and she has trouble getting to the bathroom in time. What conditions should be ruled out when determining whether she has an overactive bladder?
   A. Urinary tract infection
   B. Diabetes
   C. Hypertension
   D. A and B

6. What percentage of Americans believes that OTC medications are safe when taken as directed?
   A. 60%
   B. 67%
   C. 87%
   D. 92%

7. What is the fastest-growing category among OTC medications?
   A. Glucosamine
   B. Analgesics
   C. Probiotics
   D. All of the above

8. A patient who is using lansoprazole is interested in trying a less-expensive store brand, but she seems reluctant. She is concerned it will not work as well as the branded product. What information might assure her about the quality of store-brand OTC lansoprazole?
   A. The FDA holds store brand manufacturers to a different level of compliance than national brand manufacturers.
   B. The FDA holds store brand manufacturers to the same level of compliance as national brand manufacturers.
   C. The FDA holds store brand manufacturers to a higher level of compliance than national brand manufacturers.
   D. The FDA does not regulate store brand manufacturers.

9. When discussing the use of lansoprazole, what should you discuss with this patient while she is in the office?
   A. Risk of fracture with long term PPI use
   B. Constipation is a common side effect
   C. She should take the medicine every day for 6 months
   D. Risk of alopecia with this product
10. Mrs. Anderson is at your clinic with her 17-year-old daughter, who has a documented strep throat. As you are writing a prescription for an antibiotic, Mrs. Anderson asks if it is all right to use acetaminophen to help reduce her daughter’s fever. What should you discuss with her regarding appropriate use of acetaminophen?
   A. Risk of secondary hypertension
   B. Risk of liver damage and severe skin reaction
   C. Interaction with antibiotics
   D. Risk of renal damage

11. What treatment is currently recommended in guidelines for mild persistent allergic rhinitis?
   A. Antihistamine alone
   B. Intranasal corticosteroid alone
   C. Antihistamine or intranasal corticosteroid
   D. Combination of antihistamine and intranasal corticosteroid

12. Emergency contraception must be taken:
   A. Within 12 hours of unprotected intercourse
   B. Within 24 hours of unprotected intercourse
   C. Within 72 hours of unprotected intercourse
   D. Within 5 days of unprotected intercourse

Complete Post-Test and Evaluation online at www.ProCE.com/OTC-clinical