

1. INTRODUCTION

Over-the-counter (OTC) medications—drugs available to consumers without a prescription—play an increasingly vital role in our healthcare system and are the most prevalent means of treating the majority of common health problems in the United States. There are over 80 therapeutic categories of OTC drugs which can be grouped in 12 broad therapeutic classes. [1,2] (See Table 1)

<ul style="list-style-type: none">• Analgesics and antipyretics• Cold, cough, and allergy products• Nighttime sleep-aids• Gastrointestinal products• Dermatological products• Other topical products (including dermal and vaginal antifungals, anorectal medications, head lice products, hair loss products, and otics)	<ul style="list-style-type: none">• Ophthalmic products• Oral health care products• Menstrual products• Nicotine replacement products• Weight loss aids• Vaginal contraceptives and emergency contraceptives
--	---

OTC retail sales totaled \$17 billion (excluding Walmart sales) in 2010. [3]

Currently, 35% of adult Americans use OTC medications on a regular basis and there is a trend for increasing use as more drugs move from prescription to OTC status. [4]

The Center for Drug Evaluation and Research (CDER) division of the Food and Drug Administration (FDA) regulates OTC medications to ensure that they are properly labeled, their benefits outweigh their risks, their potential for misuse and abuse is low, and that health practitioners are not needed for their safe and effective use. [1]

The benefits of over-the-counter availability include: [5,6]

- Direct, rapid access to effective medicines
- Wide availability
- Decreased healthcare system utilization (fewer physician visits, lower healthcare system costs)
- Allowing individuals to be in charge of their own health

However, there are risks associated with OTC use, such as: [5,6]

- Incorrect self-diagnosis delaying diagnosis and treatment of serious illnesses (delay in seeking advice from a healthcare professional)
- Increased risk of drug-drug interactions
- Increased risk of adverse events when not used appropriately
- Potential for misuse and abuse

2. CLARIFYING TERMINOLOGY

One area of confusion is the definition of and demarcation between drugs, dietary supplements, and cosmetics. FDA's definitions of these categories are provided in the following. While FDA does not use the term "OTC medications," we use it in this material interchangeably with "OTC drugs."

Drugs / OTC Drugs

Drugs (prescription and OTC drugs) are substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. OTC drugs are defined as safe and effective for use by the general public without a doctor's prescription. [7]

Dietary Supplements (including Herbal Ingredients)

A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. Permitted ingredients of dietary supplements include vitamins, minerals, herbs or other botanicals, and amino acids. [8]

Cosmetics

Cosmetics are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body... for cleansing, beautifying, promoting attractiveness, or altering the appearance." [9]

Another area of confusion exists around the terms therapeutic error, misuse, and abuse. In order to clarify these terms, the following definitions by the American Association of Poison Control Centers (AAPCC) are supplied. [10]

Therapeutic error: An unintentional deviation from a proper therapeutic regimen that results in the wrong dose, incorrect route of administration, administration to the wrong person, or administration of the wrong substance.

Intentional misuse: An exposure resulting from the intentional improper or incorrect use of a substance for reasons other than the pursuit of a psychotropic or euphoric effect.

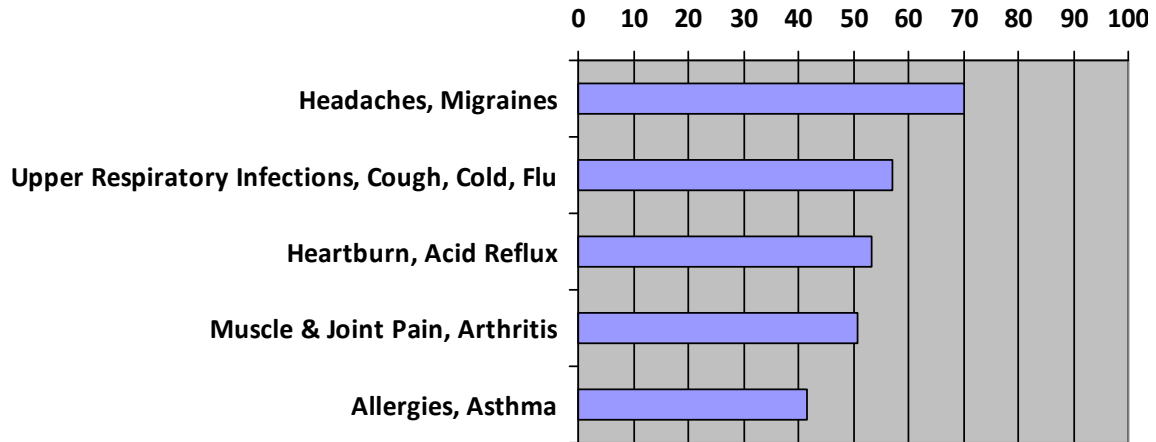
Intentional abuse: An exposure resulting from the intentional improper or incorrect use of a substance where the individual was likely attempting to achieve a euphoric or psychotropic effect.

3. USE IN THE GENERAL POPULATION

The use of OTC medications is one aspect of a growing movement toward medical self-care and has become a tool in gaining control over one's health. The findings of a 1999 Slone survey of adult Americans demonstrated the important role OTC medicines have in the general population. In this study, OTC analgesics were the most frequently used of all medications (OTC or prescription), taken by approximately 20% of the population in a given week. OTC decongestants and antihistamines followed analgesics in frequency of use. [11]

Female individuals are more likely to use OTC medications. [12] In a 2002 survey, 87% of women reported the use of an OTC pain medication in the past year compared to 80% of men. [13] A study conducted in 2011 confirmed that OTC medications are American's most popular treatment choice for common ailments such as headache, heartburn, allergies, and colds. [14] (*See Figure 1*)

Figure 1. Percentages of Individuals Who Treated a Condition With OTC Products Only (n=1,880; January 2011) [14]



The most commonly used OTC products in the United States according to 2009 sales data are (expressed as number of pack units sold in 2009; excluding Walmart data): [15]

- OTC MEDICATIONS FOR ORAL INGESTION
 - Cough/cold and allergy remedies (711,604,074)
 - Analgesics (430,254,703)
 - Antacids and anti-gas products (173,320,632)
 - Laxatives (114,872,050)
 - Diarrhea remedies (22,663,194)

- OTC MEDICATIONS FOR TOPICAL USE
 - Toothpastes (458,370,150)
 - Oral antiseptics and rinses (178,368,512)
 - First aid treatments* (157,717,515)
 - Lip remedies (151,111,158)
 - Eye care products (62,401,048)

* Including germicidal antiseptics and topical hydrocortisone

4. USE IN SPECIAL POPULATIONS

Children. The number of children ages 12 and younger being administered an OTC medication in a given time period is more than twice that of prescription medications. The most commonly used OTC medications in children are the analgesics/antipyretics acetaminophen and ibuprofen. [16]

Adolescents. Compared to the general population, adolescents 12–17 years of age use more OTC products for acne and less for allergies and pain relief. Use by adolescents accounts for 38% of acne remedies' sales volume, but for only 7% of the total internal analgesics category volume. [17] Of particular concern are adolescents who abuse alcohol, illicit drugs, and medications including OTC cough medicines containing dextromethorphan. The 2011 Monitoring the Future survey, which looks at 8th, 10th, and 12th graders nationwide, showed that in 2010 approximately 5% of the survey participants reported past year use of OTC cough medicine "to get high." For comparison, the ratio of 8th, 10th and 12th graders in this survey reporting the abuse of other substances within the past year was 49% for alcohol, 25% for marijuana, 6% and 4% for the prescription analgesics Vicodin[®] and OxyContin[®], respectively. [18]

Older adults. Adults ages 65 years and over generally have more medical problems and use more medications, both prescription and OTC, when compared to younger adults. In this group, polypharmacy is common including multiple OTC preparations and prescription drugs. Age-related changes occur in the elderly, predisposing this population to greater risks of adverse events, drug-drug interactions, therapeutic errors, and misuse. [19,20,21] Physicians should refer to the Beers List of drugs potentially inappropriate

for the elderly when prescribing and counseling patients regarding OTC drug use. The latest update of Beers List has been published in the *Archives of Internal Medicine* and is available at: <http://archinte.ama-assn.org/cgi/content/full/163/22/2716#ACK>. [21] OTC medications of particular concern include diphenhydramine (can cause confusion and sedation), nonsteroidal anti-inflammatory drugs (renal dysfunction, gastrointestinal bleeding, hypertension, exacerbation of heart failure), ferrous sulfate (constipation), and mineral oil (aspiration, lipid pneumonia) due to their increased risk of adverse events in older adults.

5. THERAPEUTIC ERRORS AND MISUSE

While the public acknowledges the need to be careful with using OTC medications, therapeutic errors and misuse occur with these products. The root causes of therapeutic errors and misuse of OTC medicines are attributable to inaccurate attitudes and wrong beliefs. For instance:

- One third (33%) of Americans admit that they have taken more than the recommended dose of an OTC medicine [22]
 - thinking it will bring more relief more quickly,
 - thinking it will help with severe symptoms, or
 - because they did not obtain relief after taking the recommended dose.
- While 95% of Americans read some portions of the OTC label, only half (51%) say they seek out the packaging label for usage information when they plan to take an OTC medication for the first time. [22]
- Given the scale of OTC medication use, a significant number of individuals are likely to take more than one prescription or OTC drug simultaneously, which can increase the risk of drug-drug interactions. [23]
- Areas of intentional incorrect use or misuse of OTC medicines include:
 - using more than the recommended doses of pain relievers [13],
 - using laxatives to lose weight and to “feel thin” (in particular by individuals with eating disorders) [24], and
 - using first-generation H1-antihistamine allergy medicines to sedate young children. [25]

Therapeutic errors and misuse of OTC medications are associated with medication overdoses and adverse events.

- In 1999, the FDA estimated the ratio of hospitalizations due to adverse events from all medications (prescription and OTC) to be 5.5%, and the ratio of hospitalizations due to adverse events specifically from OTC drugs to be 0.55% (corresponding to 170,500 of 31 million annual hospitalizations). [26]
- A study of 2004/2005 data by the Centers for Disease Control and Prevention (CDC) showed that over 70,000 children annually were brought to emergency departments for medication overdoses (in more than 26,000 of these cases, OTC medications were implicated). Four fifths (82%) of emergency department visits for medication overdoses resulted from resulting from unsupervised ingestions of prescription and OTC drugs, with peak incidence in two-year-olds. [27]

6. STORAGE AND DISPOSAL

Medications need to be properly stored for maximal safety and efficacy. If incorrectly stored, children may ingest harmful doses of OTC drugs. As the aforementioned study by the CDC showed, medication

overdoses resulting from unsupervised ingestions of OTC and prescription products is a main cause of emergency department visits by young children. [27]

For proper disposal, the Environmental Protection Agency recommends that drugs be taken out of their containers, mixed with undesirable substances, (e.g., cat litter, used coffee grounds) and put into a disposable container with a lid or into a sealed bag before putting in the trash. Advise patients to remove any personal information from any labels by covering the information with black marker, or duct tape, or by scratching it off. [28]

Environmentally, it is irresponsible to “flush” OTC medications. Most sewage treatment plants are not equipped to extract pharmaceutical compounds from wastewater and the impact of these drugs in public drinking water is unknown. [28]

7. DOCTOR/PATIENT COMMUNICATION GAPS

As common as OTC use is, there appear to be significant challenges for doctors to communicate with their patients about it. For instance:

- While three-quarters of physicians report that they ask their patients directly about OTC drug use, one-quarter waits for patients to volunteer this information. [22]
- Americans are least likely to talk with a medical professional about taking more than the recommended dose of an OTC medication (30%), the use of leftover prescription antibiotics (33%), the use of OTC pain relievers (36%), and the use of more than one OTC product at a time. [22]
- Only 18% of physicians educate their patients about safe drug taking, storing, and disposal practices. [29]

8. PHYSICIAN’S ROLE – WHAT DOCTORS SHOULD TELL THEIR PATIENTS

Due to the high prevalence of OTC medication use, physicians need to stay abreast of the trends in OTC usage patterns as well as the risks associated with incorrect use and storage of OTC drugs.

Physicians need to participate in efforts to prevent adverse events, therapeutic errors, misuse, and unsupervised pediatric ingestions of OTC medicines.

- Routinely document OTC use in the medical history:
 - to detect incorrect use,
 - to detect potential drug-drug interactions, and
 - to identify therapeutic duplication.
- Discuss with patients the potential risks of the OTC medications they have disclosed during history taking.
- Provide alternative medication choices if you suspect misuse of an OTC medication.
- Teach patients how to read package labeling with special emphasis on the sections “Warnings” and “Directions” (dosage instructions).
- Teach parents and caregivers about the use of OTC medications in children.
 - Emphasize the importance of heeding the dosage instructions of the package labeling.

- Teach parents and caregivers about the handling and storage of OTC medications.
 - Tell your patients to put the entire container up, away, and out of sight after every use.
 - Tell your patients to correctly replace the child-resistant caps on all medicines.
- Refer patients to Internet educational resources (*See Patient Guide and Patient Education Resources*).

Following are a few scripted conversations that may help with the discussion.

Ten Important Conversations:

1. “Tell me about the types of OTC medications you take.”
2. “Read the entire package label and follow its instructions each time a dose is taken. In particular, if you take more than one medicine, pay attention to the active ingredients stated on the label to avoid taking too much of the same active ingredient.”
3. “Contact me at any time if you have questions about the choice or use of an OTC medication.”
4. “Contact me if you feel you need a dose that is higher than the one recommended on the package label.”
5. “Keep all medications in their original container.”
6. “Correctly replace the child-resistant caps on all medicines after every use.”
7. “Keep OTC and prescription drugs out of reach and sight of children after every use.”
8. “Make a general house policy that all drugs are stored in one well-controlled location such as a locked drawer or cabinet, and that no drugs are stored in bedrooms, automobiles, backpacks, or school lockers.”
9. “Discard all medications that have expired. Regardless of the expiration date, discard any medications that show changes in shape, size, color, or odor; show signs of softening, cracking, or hardening; when tablets or capsules stick together; or when a liquid has become cloudy.”
10. “To discard drugs take them out of their containers, mix them with undesirable substances (e.g., cat litter, used coffee grounds), and put them into a disposable container with a lid or into a sealed bag before putting in the trash. Remove any personal information by covering the information with black marker, or duct tape, or by scratching it off.”

9. BOTTOM LINE

OTC medications represent a diverse group of widely available drugs. OTC use is ever increasing and expected to continue to rise. These drugs are safe and effective when used as directed. However, physicians must be aware that some people--with or without intention--use OTC medications incorrectly. Instruct all patients on the safe and appropriate storage and disposal of all types of medicines. Stay abreast of trends in OTC usage, therapeutic errors, misuse, and abuse. Routinely incorporate OTC conversations during office visits. A list of physician and patient resources is below. Each of these efforts will help your patients to get the maximum benefit out of OTC use while minimizing the risks of incorrect OTC use.