Self-Care Specialist (SCS) Unit 1: Introduction to Self-Care
Pete Kreckel, RPh

Live Activity Handout
2 slides per page
Specialty Certification Self-Care Specialist (SCS) Unit 1: Introduction to Self-Care

ACTIVITY DESCRIPTION
This activity is an introduction to over-the-counter drug therapy designed to make the pharmacist understand the scope and cost savings of OTC medications. A brief history of the laws that govern OTC products as well as approaches to helping patients make informed self-care choices. Although the behind the counter concept does exist, and is currently underutilized participants will see the need for expansion for that category. Join “Professor Pete” Kreckel a pharmacist with nearly four decades of community pharmacy experience as he lays the groundwork for a fifteen-unit course that when completed will make the pharmacist a self-care expert.

TARGET AUDIENCE
The target audience for this activity is pharmacists, pharmacy technicians, and nurses in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES
After completing this activity, the pharmacist will be able to:
• Identify the cost saving benefits of Over-The-Counter medications in the health care system
• List the legislation over the past century that governs the counter sales
• Describe the pharmacist’s role in OTC consultation with regard to product selection and dosing accuracy
• Recognize the role of packaging requirements with respect to labeling and tamper evident seals.

After completing this activity, the pharmacy technician will be able to:
• Identify the cost saving benefits of Over-The-Counter medications in the health care system
• List the legislation over the past century that governs the counter sales
• Recognize the role of packaging requirements with respect to labeling and tamper evident seals.

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ABOUT THE AUTHOR

“Professor Pete” Kreckel is a practicing retail pharmacist who works in Altoona, Pennsylvania. Both he and his wife, Denise are 1981 graduates of the University of Pittsburgh School of Pharmacy. He has worked independent retail pharmacy for over 30 years. He has been teaching Pharmacology in the Physician Assistant program at St. Francis University since 2005. He has been a regular PharmCon favorite since 2008 covering topics of primary interest to the retail pharmacist. He was inducted into Pi Alpha the Physician Assistant honorary fraternity, and was named as “Preceptor of the Year” by the Pennsylvania Pharmacists Association for his dedicated work to the education of pharmacy students from Duquesne University, and from his alma mater the University of Pittsburgh. Professor Kreckel was recently named the 2014 Preceptor of the Year by the NCPA!

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Unit 1: Introduction to Self-Care

Learning Objectives

• Identify the cost saving benefits of Over-The-Counter medications in the health care system
• List the legislation over the past century that governs over the counter sales
• Describe the pharmacists role in OTC consultation with regard to product selection and dosing accuracy
• Recognize the role of packaging requirements with respect to labeling and tamper evident seals.
Four Attributes of OTC self-care

- OTC medicines provide ACCESS 24/7 to conveniently available healthcare options for busy families and caregivers.
- OTC medicines provide AFFORDABLE treatment options for both consumers and the U.S. healthcare system.
- OTC medicines EMPOWER individuals and families to meet their everyday healthcare needs.
- OTC medicines are a TRUSTED first-line of defense for healthcare providers and consumers alike.

http://www.chpa.org/OTCvalue.aspx

The CHPA (Consumer HealthCare Products Association) says-

FIRST-LINE TREATMENT

From head to toe, consumers and physicians agree OTC medicines are the preferred first line of treatment.
We save Big Dollar$ !! X 7 !!

- Each dollar spent on OTC medicines saves $6-7 for the U.S. healthcare system. ($1.60 drug savings; $4.90 clinician visits)
- 240 million people in the U.S. currently use OTC medicines—60 million of them would not seek alternative (e.g., Rx) treatment if OTC medicines were not available.
- If OTC medicines did not exist, an additional 56,000 medical practitioners would need to work full-time to accommodate the increase in office visits by consumers seeking prescriptions for self-treatable conditions.
- If OTC medicines were not available, additional Emergency Department visits, primarily by patients on Medicaid and uninsured individuals, would drive up nearly $4 billion in healthcare system costs each year.

Not to mention....

Rx drugs that become OTC, become affordable!
- Prilosec RX ($200/30)
  - Prilosec OTC ($20.00/30)
- Zaditor RX ($80)
  - Zaditor OTC ($15)
- Nexium 20mg Rx ($300)
  - Nexium OTC ($22)
- Nasacort ($130)
  - Nasacort OTC ($26)
- Claritin, Allegra, Zyrtec---(all were over $3.00/tablet)
  - Generics are less than $3.00 per package
Definitions - let's ask the FDA

**Prescription drugs are:**
• Prescribed by a doctor
• Bought at a pharmacy
• Prescribed for and intended to be used by one person
• Regulated by FDA through the New Drug Application (NDA) process.
  • This is the formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States.
  • An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100101.htm

**OVER THE COUNTER**

**as defined by the FDA**

**OTC drugs are:**
• Drugs that do NOT require a doctor's prescription
• Bought off-the-shelf in stores
• Regulated by FDA through OTC Drug monographs.
  • A kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.
  • Are updated to add additional ingredients and labeling as needed.
  • Products conforming to a monograph may be marketed without further FDA clearance, while those that do not, must undergo separate review and approval through the "New Drug Approval System."

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100101.htm
Laws, laws and more laws!

- FDA act 1906
- FDC act 1938
- Durham Humphrey 1951
- Anti-Tampering Act of 1983

Food and Drug Act of 1906:

- The law, which prohibited misbranded and adulterated foods, drinks, and drugs in interstate commerce, was enforced by the Bureau of Chemistry in the Department of Agriculture. The bureau became the Food and Drug Administration in 1930.

- There was no requirement, that any information be submitted to the FDA before marketing, and the law required only that drugs meet standards of strength and purity.
Federal Food, Drug and Cosmetic Act 1938

• Elixir of Sulfanilamide Tragedy: The S.E. Massengill Co. of Bristol, Tenn., had been marketing the product, which was the chemical relative of antifreeze now used in automobiles. 107 people died.
• For the first time, manufacturers were required to show that a drug was safe before it could be marketed.

The First OTC Law

1951 – Durham Humphrey Bill sets up prescription and non-prescription categories for all medicines. Took effect in 1952. This arrangement of prescription vs. OTC is in place by policy and is then made law.
It also sets up limits on the number of times a prescription can be refilled
Sen. Hubert Humphrey: RPh from South Dakota
Kefauver-Harris Drug Amendments of 1962

• In October 1962, Congress passed amendments to the Federal FD&C Act.
  • Before marketing a drug, firms now had to prove not only safety, but also provide substantial evidence of effectiveness for the product's intended use.
  • "That evidence had to consist of adequate and well-controlled studies, a revolutionary requirement."
• Drug companies had to have FDA approval before marketing a drug.

Memories...OTC care is ever changing

• Parepectolin® Donnagel-PG®
• Ipecac
• Nitre
• Mercurochrome ® (merbromin)
• Alupent® (metaprotenerol) (1982-pulled 1983)
• Merthiolate® (thiomersal)
• Camphorated oil
Pharmacist role in OTC product consultation

- One of six adults admit taking three or more pills in single dose, despite label recommendations
- 47% children given wrong dose of OTC fever medicine
- OTC labels: Drug Facts hard to understand. Example: Tylenol infant drops vs. Tylenol elixir.
  - 1 teaspoonful of infant drops = 500mg (NO LONGER AVAILABLE)
  - 1 teaspoonful of elixir = 160mg

QuEST- Process for OTC consultation

- **Q**uickly and accurately assess the patient
- **E**stablish that the patient is an appropriate self care candidate
- **S**uggest appropriate self care strategies
- **T**alk with the patient

SCHOLAR

• Symptoms
• Characteristics
• History
• Onset
• Location
• Aggravating factors
• Remitting factors

Ask open ended questions??

• An open-ended question is designed to encourage a full, meaningful answer using the subject's own knowledge and/or feelings.
• It is the opposite of a closed-ended question, which encourages a short or single-word answer.
• Open-ended questions also tend to be more objective and less leading than closed-ended questions.
  • Can you tell me about your symptoms? (open)
  • Do you have a cough? (closed)
  • Do you have congestion? (closed)
  • Do you have a fever? (closed)
Pediatrics

• No antihistamines OTC under age 6 except loratadine, cetirizine, fexofenadine
  • Loratadine dosed down to age -2
  • Cetirizine dosed down to age -2
  • Fexofenadine dosed down to age -2
  • Diphenhydramine dosed down to age 6
• Dextromethorphan: don’t give if under age-4
  • DM polistirex dosed down to age-4
  • Children’s Mucinex Cough (DM + guaifenesin) dosed down to age-4
  • Do not give guaifenesin to a child younger than 4 years old. (drugs.com)

Pediatrics- getting the dose right
http://www.chpa.org/volguid.aspx

Use of a common household teaspoonful may vary from 4mL to 8.8mL. (source: Kreckel kitchen)

**Key changes to the voluntary guidelines include:**
• Deleting “spoon” labeling (i.e., teaspoon, tablespoon) on dosing directions and dosing devices,
• Specifying use of “mL” only in dosing directions and on devices, and
• Deleting the provision in dosing directions of a definition of any volumetric unit of measure (i.e., mL = milliliter).
Remitting Factors---PREGNANCY

• Liability issues
• Pay attention to pregnancy warnings on OTC drugs
• If a pharmacist recommends OTC products to a pregnant woman and fetal harm occurs, burden of proof rests on the pharmacist
• Most prudent advice would be to refer patients to obstetrician

Remitting Factors - Age
source: Merck Manual

• Absorption: Despite an age-related decrease in small-bowel surface area, slowed gastric emptying, and an increase in gastric pH, changes in drug absorption tend to be clinically inconsequential for most drugs. (exception: Calcium Carbonate)

• Distribution: With age, body fat generally increases and total body water decreases. Increased fat increases the volume of distribution for highly lipophilic drugs (eg, diazepam, chlordiazepoxide) and may increase their elimination half-lives.
Remitting Factors: Age

- **Hepatic metabolism**: Hepatic metabolism of cytochrome P-450 drugs decreases 30-40% with age.
  - No major decrease with conjugation.
  - First pass metabolism: See 1% per year decrease after age 40

- **Renal elimination**: Most important pharmacokinetic changes associated with aging. After age 30, creatinine clearance decreases an average of 8 mL/min/1.73 m$^2$/decade; however, the age-related decrease varies substantially from person to person

Risk management strategies

- Don’t answer drug safety questions over the telephone.
- Insist that patients come to the pharmacy.
- Patients should be required to visit the pharmacy for education related to **drug safety**.
  - Encourage patients to use on-line resources if patient won't come to pharmacy.
  - Have patients call insurance company's nurses
  - Can consult family practitioner if needed
Once the patient comes to the Pharmacy...

To decrease liability risk....

• Resources---Use the products official drug label “Drug Facts”

• Privacy---consult in the patient education area of the pharmacy

• Document! – no documentation– no discussion occurred

The Facts on Drug Facts: Acetaminophen

• Pediatric dose is considered to be 10-15mg/kg q4-6hr

• Drug Facts on Tylenol® box says under 24lb or under 2 years “ask a doctor”

  • “Ask a doctor before use if your child has liver disease”

  • “Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin”

  • “Do not use with any other drug containing acetaminophen. If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist.”
“Drug Facts” Acetaminophen Adult dose

**Tylenol®**: “The maximum daily dose of this product is 6 caplets (3000mg) in 24 hours. Severe liver damage may occur if you take more than 4,000mg in 24 hours.”
  - “Ask a doctor before use if you have liver disease.”
  - “Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin”

**Non-Aspirin 500mg**: “Do not take more than 8 tablets in 24 hours” (=4000mg)

**Non-Aspirin Arthritis 650mg**: “Do not take more than 6 caplets in 24 hours” (=3900mg)

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**Drug Facts**

**Ibuprofen dosage:**
- OTC package: 1 tablet every 4 hours. Maximum is 6 tablets per day (1200mg)
- Rx maximum= 3200mg per day

**Naproxen dosage:**
- OTC package: 1 tablet every 8-12 hours. Maximum is 3 tablets daily (660mg)
- Rx maximum: 1650mg day limited time period ; usual max= 1100mg/day
Not “Food”---Not “Drug”
source: FDA.gov

- FDA regulates finished dietary supplement products and dietary ingredients.
- Dietary supplements regulated under a different set of regulations than those covering "conventional" food and drug products.
- Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):
  Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.

Dietary Supplements
What does the FDA do?

- Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law. Routine monitoring of products pulled from store shelves or collected during inspections of manufacturing firms.
- FDA does not analyze dietary supplements before they are sold to consumers.
- The manufacturer is responsible for ensuring that the "Supplement Facts" label and ingredient list are accurate, that the dietary ingredients are safe, and that the content matches the amount declared on the label.
Dietary supplements regulation?

- These products are not standardized or regulated in the same manner as Rx and OTC drugs. Some products do not contain the labeled amount of active ingredients or may contain contaminants.
- Dietary supplements are considered to be: vitamins, minerals, other botanicals, amino acids, enzymes, organ tissues, glandular, and metabolites.
- The **Federal Trade Commission** (FTC) regulates advertising, including infomercials, for dietary supplements and most other products sold to consumers.

Cultural biases

- Lack of eye contact in American culture is usually considered as a negative. May be interpreted as a lack of interest, embarrassment, or even depression.
- Lack of eye contact from a Chinese patient may be showing the pharmacist respect.
- Lack of eye contact if patient is female and from a Muslim country, and the pharmacist is male, she may be trying to avoid sexual impropriety.
- Direct eye contact during the initial greeting of the American Indian patient is important but prolonged eye contact is seen as a sign of disrespect.

[http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1070887/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1070887/)
What about the pills?

- Cambodians equate pill size with potency; a large tablet may be thought of as too large a dose.
- Western belief that a greater number of milligrams (mg) in a pill or capsule make a medication stronger.
- Chinese older adults may believe that Western medicine is too strong and may not take the full dose or complete the course of treatment.
- Some cultures from Latin America view injections as more effective than oral medications.
- Limited supplies of medications might have patients thinking they are not chronic medications, and discontinue too early.

Expiration Dates

- "The absence of an expiration date on any drug product packaged after September 29, 1979, is cause to initiate regulatory action against the product and/or the responsible firm."
- Exemptions: certain topical drugs, astringents, skin protectants, lotions.
- SLEP (Shelf Life Extension Program): It has found that 88% of 122 different drugs stored under ideal conditions should have their expiration dates extended more than 1 year, with an average extension of 66 months, and a maximum extension of 278 months. The SLEP is extremely cost-effective; each dollar spent on it saves $13 to $94 in medication costs. (DoD & FDA)
- We don’t have access to data - don’t recommend expired meds!
Why “tamper Evident” packaging

- In the fall of 1982, seven people in the Chicago area died after ingesting Extra-Strength Tylenol laced with potassium cyanide. The products were removed from the shelves, infected with cyanide and returned to the shelves. The crime — which has never been solved — sparked a citywide panic; for days, police cruised the streets, blaring warnings that residents should discard the product. (Time Magazine)
- It was reported that an unknown suspect/s put 65 milligrams of deadly cyanide into Tylenol capsules, 10,000 times more than what is necessary to kill a human
- In 1982, Tylenol controlled 37 percent of its market with revenue of about $1.2 million. Immediately after the cyanide poisonings, its market share was reduced to seven percent

“Tamper Evident Packaging”

- Manufacturers and packagers are free to use any packaging system as long as the tamper-resistant standard in the regulations is met. The TRP requirements are intended to assure that the product's packaging "can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

### Examples Options of Tamper Evident Packaging

- Film wrappers
- Blister or strip packs
- Bubble packs
- Heat shrink bands or wrappers
- Foil, paper or plastic pouches
- Container mouth inner seals
- Tape seals
- Breakable caps
- Sealed metal or plastic tubes
- Sealed cartons
- Aerosol containers
- Metal cans

### Transition from Rx to OTC

- The drug is switched through the non-prescription drug review process
- The manufacturer requests switch by submitting a supplemental application to an already approved New Drug Application
- The manufacturer or other party petitions the FDA. Third party payers have petitioned the FDA for Rx to OTC switch
Switching to OTC since 1976

- Sept 9th, 1976: brompheniramine, chlorpheniramine, oxymetazoline, pseudoephedrine, approved for OTC use
- #110 ingredient and dosages transferred from Rx to OTC status. Currently about 55-58 “new” products have been approved for OTC switch.

Source: http://www.chpa.org/SwitchList.aspx (Consumer HealthCare Products Association)

Other significant switches

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date</th>
<th>Drug</th>
<th>Date</th>
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<tbody>
<tr>
<td>Hydrocortisone</td>
<td>Dec 79</td>
<td>Minoxidil 2% sol</td>
<td>Dec 96</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>May 84</td>
<td>Nicotine gum</td>
<td>Feb 96</td>
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<tr>
<td>Loperamide</td>
<td>Mar 88</td>
<td>Docosanol</td>
<td>July 00</td>
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<tr>
<td>Permethrin 1%</td>
<td>May 90</td>
<td>Loratidine</td>
<td>Nov 02</td>
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<tr>
<td>Clotrimazole vag</td>
<td>Nov 90</td>
<td>Omeprazole</td>
<td>June 03</td>
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<tr>
<td>Miconazole vag</td>
<td>March 91</td>
<td>Levonorgestrel</td>
<td>Aug 06</td>
</tr>
<tr>
<td>Naproxen sod 220</td>
<td>Jan 94</td>
<td>PEG 3350</td>
<td>Oct 06</td>
</tr>
<tr>
<td>Famotidine</td>
<td>April 95</td>
<td>Orlistat</td>
<td>Feb 07</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>June 95</td>
<td>Triamcin n.s.</td>
<td>Oct 13</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>Dec 95</td>
<td>Adapalene gel</td>
<td>July 16</td>
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The Pharmacist’s Role

• The “Drug Expert”
• Understanding of disease states with respect to drug therapy.
• Understanding of the adverse drug effects (side effects) that medications over the counter can cause.
• Can “bridge the gap” between prescription and over the counter medications

Behind the Counter defined

• What does “behind-the-counter” mean? The Act defines “behind-the-counter” as placement of the product to ensure that customers do not have direct access to the product before the sale is made.
• In other words, placement may be in a secure location in the pharmacy prescription-filling area or in a locked cabinet that is located in the area of the facility to which customers do have direct access.
• In all cases, the seller will deliver the product directly into the custody of the buyer

http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm072423.htm
What about a third class of drugs? BTC: PHARMACIST RECOMMENDED!

- Varenicline (Chantix)
- Epinephrine auto injector (Epi-Pen)
- Naloxone auto injector (Evzio) (Penna LAW)
- PPI – Omeprazole (Prilosec), Lansoprazole (Prevacid), Esomeprazole (Nexium)
- H2RA: Ranitidine (Zantac), Famotidine (Pepcid), Cimetidine (Tagamet)
- Nicotine Replacement: patches, gum, lozenges, inhaler
- Nitroglycerin sublingual tablets
- Pseudoephedrine (Sudafed) (currently there)

What about a third class of drugs? BTC: PHARMACIST RECOMMENDED!

- Lipase inhibitors  Orlistat (Alli)
- Syringes (currently there)
- Vaginal yeast treatment (azole antifungals) Miconazole, Clotrimazole
- Single Entity DEXTROmethorphan products (Delsym)
- Nasal corticosteroids Triamcinolone (Nasacort); Flonase (Fluticasone)
- Naloxone (Narcan®) (currently standing orders in some states)
- Any other Rx to OTC transitions
BTC: Cost benefits, if any? (General Accounting Office “GAO”)

According to a report by the General Accountability Office titled “Pharmacist-Controlled Nonprescription Drugs,” the economic effect of creation of a three-tier system drug distribution is unclear

• If the introduction of an intermediate class permitted a drug to be switched from prescription status, the price might decline. BUT...
• It is possible that the decrease in the number of retailers selling these drugs could adversely affect retail competition and, as a result, drive up prices.

Cost Benefits - “GAO”

• If drugs were moved to the intermediate class from the general sale category, the greater role of pharmacists might lead to higher prices if a counseling fee is implemented
• If insurers elected not to cover drugs that were moved from prescription status to an intermediate class, consumers’ out-of-pocket expenditures would increase.
• The cost of obtaining a prescription drug includes not only the cost of the drug itself but also the cost of the visit to a physician. Patients would be saved the cost of the visit to the physician.”

Source: http://www.managedcaremag.com
Concerns I would have...

- Are all “pharmacists” capable of such responsibilities, with respect to disease state management?
  - Are students adequately trained for such responsibilities.
  - “Moonlighting pharmacists”
- Would additional certification be necessary?
- Would the insurance companies reimburse us as providers?
  - Billing, early refill edits, drug interactions????
  - Costs adjudicated?

Other concerns

- Collaborative practice needed?
- Who do we send our patient to if further care is necessary? (Patient uses Epi-Pen... now what?)
- Do we have the diagnostic hardware...
  - Tape measure
  - Scales
  - Cholesterol monitoring
  - How do we document all of this
- PROVIDER STATUS???
This course

• 14 more topics will be covered
• A 100 question exam will be given at course completion
• You will receive a Certification of Completion attaining the quality standard and criteria of Self-Care Specialist
• Will be in a webinar format, with complete slides
• Will be taught by Peter Kreckel, R.Ph.

Meet your presenter

• Peter Kreckel R.Ph.  1981 Graduate of the University of Pittsburgh School of Pharmacy
• Wife Denise is a pharmacist, along with daughter Gretchen Kreckel Garofoli and son-in-law Mark Garofoli
• 2012 Pennsylvania Preceptor of the Year
• 2014 National Community Pharmacy Association (NCPA) Preceptor of the Year
• Working in independent Community Pharmacy Practice since 1981
• Teaching Pharmacology in Physician Assistant Program at St. Francis University since 2005
• Lecturing for freeCE since 2008