Over the Top with OTC?
Guiding Patients Through Self-Treatment

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Disclosures

Stefanie Ferreri and Dan Krinsky declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
CPE Information

• Target Audience: Pharmacists and Pharmacy Technicians
• ACPE#: 0202-0000-19-100-L01-P/T
• Activity Type: Application-based
Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

1. Apply recent literature in the decision-making process for evaluating candidacy for self-care and selecting appropriate nonprescription products for patients.

2. Demonstrate effective educational strategies when using nonprescription products.

3. Provide guidance for safe nonprescription medication selection and nonpharmacologic interventions for patients with various conditions.
Assessment Question #1

Adapalene, the first nonprescription topical retinoid, has which acne fighting property that is different from benzoyl peroxide?

a. Antibacterial
b. Anti-inflammatory
c. Comedolytic
d. Keratolytic
In the study evaluating whether certain acetaminophen product strengths could lead to excessive dosing:

a. Users taking the 325mg strength tablet had a greater chance of exceeding 4 grams/day
b. Users who did exceed 4 grams per day of acetaminophen took an average of 5.2 grams/day
c. Users taking the 650 mg strength tablet were more likely to know the correct dosing interval
d. Regardless of the product strength a majority of acetaminophen users were likely to exceed the maximum recommended daily dose of 4 grams/day
Assessment Question #3

Which patient situation would be most appropriate for recommending an OTC epinephrine inhaler?

a. Reports no longer having a prescriber
b. Wakes nightly due to coughing/wheezing
c. Needs a prescription albuterol but it’s too soon
d. Left albuterol inhaler at home while on vacation
Assessment Question #4

Which of the following is the best predictor of sustained heartburn relief with the use of a PPI?

a. Symptom resolution within the first 3 days of therapy
b. Increased frequency of heartburn symptoms at baseline
c. Greater number of days without heartburn symptoms during treatment
d. The dose of PPI taken
Update on Dermatological Conditions

Focus on Acne
Acne Case – LM

- LM, is an 18-year-old woman who has suffered from acne for the past 2 years
- The community pharmacist has helped her in the past select several different OTC products; however, LM has had little success
- LM appears to have 10 to 20 lesions located around her jaw line and chin with several lesions appearing erythematous and pustular
- She has no involvement of her chest, back, or shoulders
Management of Acne
Background Information

• Affects 85% of people aged 12-24 years
  • Negative psychosocial effect
• Most common adolescent skin disorder
• Originates in the pilosebaceous unit in the dermis
  • Androgenic hormones stimulate sebaceous gland which produces sebum
  • Sebaceous glands are more common on face, neck, and back
• Acne is a bacteria, propionbacterium acnes (P. acnes), growing in a plugged follicle
Pathophysiology of Acne

- Inflammation
- Follicular hyperkeratinization
- P. acnes colonization
- Increased sebum

Acne
Factors that Exacerbate Acne

- Exogenous
  - Medical trauma
  - Occlusive clothing
  - Humidity
  - Air pollution
  - Harsh scrubbing of the skin
  - Oils on the skin
  - Medications

- Endogenous
  - Emotional Stress
  - Premenstrual phase
  - Hormones

- Myths
  - Foods
  - Sexual activity
Medications that can Induce Acne

- **P** Phenytoin
- **I** Isoniazid
- **M** Moisturizers
- **P** Phenobarbital
- **L** Lithium
- **E** Ethionamide
- **S** Steroids

- Azathioprine
- Haloperidol
- Rifampin
- Thyroid preparations
- Contraceptives (high progestin level)
- Dantrolene
- Androgens
- Bromides
- Iodides
Acne
Clinical features

• Increased seborrhea
• Open comedones
• Closed comedones
• Inflammatory papules
• Pustules
• Nodulocystic lesions
Acne

Open comedo: Blackhead

Closed Comedo: Whitehead
# Classification of Acne

<table>
<thead>
<tr>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Few erythematous papules and occasional pustules mixed with comedones</td>
<td>Many erythematous papules and pustules and prominent scarring</td>
<td>Extensive pustules, erythematous papules, and multiple nodules in an inflamed background</td>
</tr>
</tbody>
</table>
Acne Case – LM

• What Else Do You Want to Know?
Exclusions to Self-Care

- Unresponsiveness to OTC agents
  - No improvement after 6 weeks of self-treatment
  - Verify compliance with regimen
- Inflammatory acne
  - Psychologically better to be under the care of MD
  - Patient is on a medication that can cause acneform
- Possible rosacea
Differentiation of Acne & Rosacea

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Acne</th>
<th>Rosacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etiology</td>
<td>Increased sebum production; <em>P. acne</em></td>
<td>Unknown</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Closed / open comedones; inflammatory acne</td>
<td>Sensitivity to touch, symmetric reddening of the face</td>
</tr>
<tr>
<td>History</td>
<td>None</td>
<td>Frequent facial flushing</td>
</tr>
<tr>
<td>Incidence</td>
<td>Nearly universal</td>
<td>More common in women than men</td>
</tr>
<tr>
<td>Onset</td>
<td>Usually ages 15-24 years</td>
<td>Usually ages 20-60 years</td>
</tr>
<tr>
<td>Location</td>
<td>Face, chest, back</td>
<td>Central portion of face</td>
</tr>
<tr>
<td>Aggravating factors</td>
<td>Cosmetic use, hormones, emotional factors, medication use</td>
<td>Temperature extremes, emotional influence, alcohol, smoking, spicy foods</td>
</tr>
<tr>
<td>Remitting factors</td>
<td>Cleanse skin, minimize aggravating factors</td>
<td>Minimize aggravating factors, use sunscreen</td>
</tr>
</tbody>
</table>
• LM has two prescriptions: adapalene 0.1% cream to be applied to the affected area at bedtime and clindamycin 1% lotion to be applied to the affected area daily

• She was instructed by the dermatologist to use each product after cleansing her skin and to return in 2 months for a follow-up appointment

• When picking up her prescriptions, LM asks the pharmacist, “Why do I need 2 medications for my acne—shouldn’t I just try one to start?” How should the pharmacist respond?
Treatment of Acne

- Based on severity
  - Varies according to the number, type, and distribution of lesions
- Mild
  - Monotherapy with a topical retinoid (e.g., adapalene)
- Moderate
  - Combination therapy is often necessary
  - Erythematous and pustular (inflammatory) lesions require treatment with an agent possessing antimicrobial properties to decrease colonization of p. acnes
- Severe
### Treatment of Acne

<table>
<thead>
<tr>
<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1st line treatment</strong></td>
<td>Benzoyl peroxide (BP) OR Topical retinoid OR Topical combination therapy (BP + antibiotic (Abx) OR retinoid + BP OR retinoid + BP + Abx)</td>
<td>Topical combination therapy (BP + Abx OR retinoid + BP OR retinoid + BP + Abx) OR Oral antibiotic + topical retinoid + BP OR Oral Abx + topical retinoid + BP + topical Abx</td>
<td>Oral Abx + Topical combination therapy BP + Abx OR Retinoid + BP OR Retinoid + BP + Abx OR Oral isotretinoin</td>
</tr>
<tr>
<td><strong>Alternate treatment</strong></td>
<td>Add topical retinoid OR BP (if not on already) OR consider alternate retinoid OR consider topical dapsone</td>
<td>Consider change in oral Abx OR Add combined oral contraceptive OR oral spironolactone (females) OR Consider oral isotretinoin</td>
<td>Consider change in oral Abx OR Add combined oral contraceptive OR oral spironolactone (females) OR Consider oral isotretinoin</td>
</tr>
</tbody>
</table>
Treatment

- Noninflammatory acne (mild and / or moderate)
  - Nonpharmacological measures
  - Pharmacologic measures

- Inflammatory acne (moderate and / or severe)
  - Prescription
  - Nonprescription
## Stepped-Care Approach to the Treatment of Acne

<table>
<thead>
<tr>
<th>Step</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>• Mild soap and washes</td>
</tr>
<tr>
<td>Step 2</td>
<td>• Tretinoin OR benzoyl peroxide</td>
</tr>
<tr>
<td>Step 3</td>
<td>• Tretinoin and benzoyl peroxide OR Topical antibiotics</td>
</tr>
<tr>
<td>Step 4</td>
<td>• Step 3 products AND topical antibiotics</td>
</tr>
<tr>
<td>Step 5</td>
<td>• Step 3 or 4, PLUS oral antibiotics</td>
</tr>
<tr>
<td>Step 6</td>
<td>• Isotretinoin</td>
</tr>
</tbody>
</table>
Adapalene gel 0.1%

- First topical retinoid to go OTC
- Topical retinoids are effective in normalizing keratinization, preventing comedone formation, and improving penetration of other topical agents
- Do not possess antimicrobial properties
- Apply once daily to entire affected area (not just spots)
- Apply acne medication, moisturizer, then sunscreen
- May take 2-3 months for full effect and acne may get worse before it gets better
- May combine with benzoyl peroxide; may add topical antibiotic as step up therapy
- Can cause burning, stinging and/or dryness
## Properties of OTC Topical Acne Agents

<table>
<thead>
<tr>
<th>Property</th>
<th>Antibacterial</th>
<th>Comedolytic</th>
<th>Anti-inflammatory</th>
<th>Keratolytic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adapalene</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Benzoyl peroxide</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Salicylic acid</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sulfur</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Resorcinol w/ sulfur</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
• Due to severity of acne and evidence of inflammatory lesions, the optimal regimen for LM is a combination of a topical retinoid and an antimicrobial agent
• LM should be counseled on the unique role of each medication and the importance of initiating both therapies now
• LM should apply the topical agents to acne-prone areas of her face—not limited to individual existing lesions, because therapy is largely preventive
• Tell LM that her acne may worsen upon initiation of therapy, but she should notice an overall improvement within 1 to 2 months
Key Points – Acne

• Acne cannot be cured, but it can be controlled to prevent scarring
• Adherence to any treatment is crucial in achieving a successful outcome
• Minimizing environmental and physical factors that exacerbate acne can help limit the extent of the condition
• Medical referral should be considered for grading acne lesions and diagnosing severity
• Rx/OTC/Nondrug treatment should be tailored to the patient
Fast Case – Teething

• AF is a 6 month old who began teething and she has been drooling excessively and has been extremely fussy. Her parents are holding a box of teething medicine and they ask you how it should be used. They remember using it with their older child, but notice that there are no directions for kids under 2 years of age

• What advice do you give?
The safety of our consumers and their children is our highest priority. Based on the May 23, 2018 communication from the U.S. Food and Drug Administration regarding over-the-counter (OTC) teething products containing benzocaine, we are discontinuing the distribution and sale of Orajel™ teething products containing benzocaine. Orajel™ teething products containing benzocaine and labeling have complied with applicable and evolving FDA requirements since we acquired the brand in 2008. The discontinuation is effective immediately and includes Orajel™ Medicated Teething Gel, Orajel™ Medicated Nighttime Teething Gel, Orajel™ Medicated Daytime & Nighttime Teething Twin Pack and Orajel™ Medicated Teething Swabs. We are not discontinuing other Orajel™ products, which represent the majority of our Orajel™ offering.

In addition, we also are revising the Drug Facts Label on all over-the-counter oral health care products that contain benzocaine with an intended use other than teething to emphasize that these products should not be used for teething pain or in children under 2 years of age. In addition, we are adding warning statements to more clearly identify the risks and symptoms presented by methemoglobinemia, a rare but serious condition associated with the use of benzocaine.

For more information, please visit
www.fda.gov

or call our Consumer Relations hotline at 1-800-952-5080.

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm608325.htm
https://www.fda.gov/Drugs/DrugSafety/ucm273111.htm
Update on Analgesics
What data are available to assess acetaminophen misuse?

• This study assessed calls to Poison Centers regarding exposures to nonprescription acetaminophen-containing products

• Information obtained from The National Poison Data System (NPDS)

• Demographic and clinical features were compiled

• Individuals ≥12 years of age

• 2007–2016

Acetaminophen

Results:

- Decrease in therapeutic misuse exposures over the 10 year period:
  - 2007: 8753
  - 2016: 6278

Other data regarding exposures:

- Majority of individuals 12–29 years of age.
- Almost ¼ of exposures involved individuals taking > 1 acetaminophen-containing product
- 5.4% of individuals were hospitalized
- 51 deaths due to an exposure

Based on these findings, what can we do?

- Continue to educate
- Encourage reading of labels
- When dispensing APAP-containing Rx product, remind pts to avoid duplication/overlap with OTCs
- Counsel pts on OTC acetaminophen products and review specific dosing recommendations
Are pharmacists recommending *alternating* acetaminophen (A) and ibuprofen (I) in children with fever?

[Background: There are NO quality studies supporting this practice]

• Study evaluated recommendation practices of community pharmacists regarding alternating A and I in febrile children.

• Prospective, noncontrolled, descriptive assessment of the pediatric fever recommendations of pharmacists

• 125 pharmacists surveyed

• Mock scenario created: child with a fever: 40 pharmacists evaluated this

Ref: Chung A. An evaluation of community pharmacy recommendations regarding alternating antipyretics in children. [https://www.japha.org/article/S1544-3191(18)30320-0/pdf](https://www.japha.org/article/S1544-3191(18)30320-0/pdf)
Acetaminophen

• 56 pharmacists responded (45% response rate)
• 35 pharmacists were involved in the mock scenario

Results: Survey:
• 82% of pharmacists routinely advise alternating between A and I
• Most common: Alternate every 4 hours (28%)

Results: Mock scenario:
• 37% of pharmacists recommended alternating the treatments.
• Recommended schedule ranged from every 2 hours to every 6 hours
• Alternate every 3 hours (38%) for the mock scenario participants.

Summary: Inconsistencies all over re products and schedules
• Often leads to caregiver confusion and the possibility of overdosing

Acetaminophen

<table>
<thead>
<tr>
<th>Question</th>
<th>Study Survey</th>
<th>Mock Scenario</th>
<th>Physician Survey*</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>n</em></td>
<td>56</td>
<td>35</td>
<td>161</td>
</tr>
<tr>
<td>Recommended alternating A and I</td>
<td>46 (82%)</td>
<td>18 (51%)</td>
<td>80 (50%)</td>
</tr>
<tr>
<td><strong>Agent of choice for fever</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>33 (59%)</td>
<td>11 (31%)</td>
<td>106 (66%)</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>11 (20%)</td>
<td>12 (34%)</td>
<td>48 (30%)</td>
</tr>
<tr>
<td>Either</td>
<td>9 (15%)</td>
<td>6 (17%)</td>
<td></td>
</tr>
<tr>
<td><strong>Alteration schedule recommended</strong></td>
<td>n=43</td>
<td>n=13</td>
<td>n=55</td>
</tr>
<tr>
<td>q2h</td>
<td>9 (21%)</td>
<td>3 (23%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>q3h</td>
<td>9 (21%)</td>
<td>5 (38%)</td>
<td>12 (22%)</td>
</tr>
<tr>
<td>q4h</td>
<td>12 (28%)</td>
<td>4 (31%)</td>
<td></td>
</tr>
<tr>
<td>q6h</td>
<td>7 (16%)</td>
<td>1 (8%)</td>
<td></td>
</tr>
<tr>
<td>ACET q4h + IBU q6h</td>
<td></td>
<td></td>
<td>26 (47%)</td>
</tr>
<tr>
<td><strong>Basis for recommendation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experience 42 (75) (14)</td>
<td></td>
<td>42 (75%)</td>
<td></td>
</tr>
<tr>
<td>Journal articles 11 (20) (16)</td>
<td></td>
<td>11 (20%)</td>
<td></td>
</tr>
<tr>
<td>American Academy of Pediatrics 4 (7) (29)</td>
<td></td>
<td>4 (7%)</td>
<td></td>
</tr>
<tr>
<td>Opinions of mentors and colleges 8 (14) (26)</td>
<td></td>
<td>8 (14%)</td>
<td></td>
</tr>
<tr>
<td>School 14 (25) (15)</td>
<td></td>
<td>14 (25%)</td>
<td></td>
</tr>
<tr>
<td>Specific references 6 (11)</td>
<td></td>
<td>6 (11%)</td>
<td></td>
</tr>
</tbody>
</table>


Acetaminophen

Do patients exceed the maximum recommended acetaminophen dose?

- Another recent study evaluated whether certain APAP product strengths increased chances of a pt exceeding recommended max daily dose of 4 grams
- 325 mg, 500 mg, 650 mg OTC single-ingredient (SI) acetaminophen products.
- Multiyear observational study
- Enrollees asked to document daily APAP use via diaries x 7 days
- 7579 adults who used an OTC APAP product during the study period
- Goal was to identify those who exceeded 4 gm/day, based on each strength

Acetaminophen

• Users of 325mg or 500mg strengths NOT more likely to exceed 4 gm/day

• Users who took 650-mg extended-release (ER) formulations:
  • greater chance of exceeding 4 grams/day (8.9% of days vs. 4.4% with lower strengths; \(P < 0.0001\))
  • Median dose on those days was 5.2 g
  • Less likely to know the recomm dosing interval of 8 hours
  • More likely to redose too soon
  • More likely to use other acetaminophen medications concomitantly

Authors recommend the following:

• Improved labeling and information on packing of the 650mg strength products
• Enhanced pharmacist counseling of pts who purchase the 650mg strength products

Acetaminophen

Study designed to assess user’s knowledge of acetaminophen-containing medication directions

• 9629 participants
• Asked to respond to questions via a web-based panel diary study
• Participants asked about ingredients in and dosing of all OTC meds taken during a 7 day period
• Goal: assess knowledge of acetaminophen-containing meds
• Conducted from 2012-16
• Participants had to accurately answer all questions about their meds
• Participant responses evaluated for accuracy regarding ingredients, dosing, directions

**Acetaminophen**

**Results**

- 5161 participants only used 1 APAP-containing med: 2/3 knew the ingredient
- 4468 participants used 2 or more and only 1/3 knew the ingredients
- Ingredient knowledge was highest for single-ingredient medications (74%)
- Use of combination medications ranged from 39% (cough or cold) to 61% (sleep or other non-pain).
- About one-third knew to avoid concomitant use of multiple acetaminophen medications

Acetaminophen

• 85% knew the maximum one-time OTC dose
• 47% knew the minimum interval between doses
• Correct knowledge was inversely associated with not following label directions
• Knowing the one-time dose decreased the odds of taking too much at one time
• Knowing both the ingredient and that other acetaminophen-containing products should not be used decreased the odds of concomitant use by 50%.

Summary:

• Knowledge of directions for safe use of acetaminophen-containing medications is poor
• Lack of knowledge is associated with not following label instructions.
• Consumers need more education regarding safe use of acetaminophen-containing medications, particularly for combination products.

In what situations is overuse of acetaminophen likely?

- Adults who had used some form of acetaminophen were surveyed
- March 2011-March 2016; Respondents recruited via emails
- Nothing in the recruiting materials indicated study was specifically addressing acetaminophen
- Once enrolled participants received QD emails for 7 days requesting completion of an online diary regarding the medications they took the previous 24 hours
- Participants were given a list of meds from which to choose (n=423)
- They could also create a list of personal meds they were using from which they could choose

Acetaminophen

- Data evaluated based on the type of product, ingredients, time of year used
- 980K invitations sent
- 18,689 completed all 7 days of diaries + an exit interview

Participant demographics:
- Median age: 44
- 61% female
- 46% had annual income <$50K

Acetaminophen

Results:
• 14,481 used some form of acetaminophen
  • 55.2% used acetaminophen ≥ 4 of the 7 days
  • 6.3% used >4 grams daily for at least 1 day
  • 1.2% used >8 grams daily for at least 1 day
  • 1.4% used >4 grams daily for ≥ 4 of the 7 days

During cold/flu season:
• Use of combination upper resp OTC products (incl APAP) increased
• Use of combination sleep + pain OTC meds (incl APAP) was ~ same
• Use of single ingredient OTC APAP products decreased

Analgesics and Dentistry

• Opioid crisis: Decreased # of Rx’s and amounts of pain meds for minor procedures
• Change more common in areas such as emergency med and dentistry

Recent study from Japan looked at effectiveness of various medications for post-op dental pain

• 128 patients undergoing minor dental surgery
• Randomized to 4 groups to receive a single med dose immediately prior to procedure
  • Diclofenac 50mg
  • Celecoxib 400mg
  • Acetaminophen 1000mg
  • Placebo

https://doi.org/10.2344/anpr-65-01-02
Analgesics and Dentistry

- All patients received standard weight-based anesthesia peri-operatively
- Post-op pain assessed by Visual Analog Scale (VAS) at 4, 5, and 6 hrs after med dose
  - Fentanyl via PCA was available for pain mgmt. post-op; no difference in doses
- All pts receiving a med pre-op had lower VAS scores post-op compared with placebo
- All 3 treatment groups: similar level of pain relief
- Non-statistical difference between acetaminophen and other 2 groups at 4 hours

**Authors concluded:**
- acetaminophen is an option to decrease post-op pain
- ? combination of APAP + traditional NSAID may be more effective

### Table 1. Efficacy data from high-quality studies for analgesic agents

<table>
<thead>
<tr>
<th>DRUG OR DRUG COMBINATION, DOSE</th>
<th>NNTB</th>
<th>95% Conf Interval</th>
<th>At least 50% Maximum Pain Relief over 4-6 hrs (%)</th>
<th>Mean or Median, time to remedication (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Active</td>
<td>Placebo</td>
</tr>
<tr>
<td>Ibuprofen Plus Acetaminophen, 400 Milligrams/1,000 mg</td>
<td>1.5</td>
<td>1.4-1.7</td>
<td>72</td>
<td>6</td>
</tr>
<tr>
<td>Ibuprofen Plus Acetaminophen, 200 mg/500 mg</td>
<td>1.6</td>
<td>1.5-1.8</td>
<td>69</td>
<td>6</td>
</tr>
<tr>
<td>Acetaminophen Plus Oxycodone, 1,000 mg/10 mg</td>
<td>1.8</td>
<td>1.6-2.2</td>
<td>68</td>
<td>13</td>
</tr>
<tr>
<td>Ibuprofen (Fast-Acting), 200 mg</td>
<td>2.1</td>
<td>1.9-2.4</td>
<td>57</td>
<td>10</td>
</tr>
<tr>
<td>Ibuprofen (Fast-Acting), 400 mg</td>
<td>2.1</td>
<td>1.9-2.3</td>
<td>65</td>
<td>18</td>
</tr>
<tr>
<td>Ibuprofen Plus Caffeine, 100 mg/200 mg</td>
<td>2.1</td>
<td>1.9-3.1</td>
<td>59</td>
<td>10</td>
</tr>
<tr>
<td>Acetaminophen Plus Codeine, 800-1,000 mg/60 mg</td>
<td>2.2</td>
<td>1.8-2.9</td>
<td>53</td>
<td>7</td>
</tr>
<tr>
<td>Ibuprofen Plus Caffeine, 100 mg/100 mg</td>
<td>2.4</td>
<td>1.9-3.1</td>
<td>43</td>
<td>0</td>
</tr>
<tr>
<td>Ibuprofen (Acid), 400 mg</td>
<td>2.5</td>
<td>2.4-2.6</td>
<td>52</td>
<td>12</td>
</tr>
<tr>
<td>Ibuprofen (Acid), 600 mg</td>
<td>2.7</td>
<td>2.4-2.7</td>
<td>77</td>
<td>40</td>
</tr>
<tr>
<td>Naproxen, 400-440 mg</td>
<td>2.7</td>
<td>2.2-3.5</td>
<td>49</td>
<td>11</td>
</tr>
<tr>
<td>Ibuprofen (Acid), 200 mg</td>
<td>2.9</td>
<td>2.7-3.2</td>
<td>41</td>
<td>7</td>
</tr>
<tr>
<td>Acetaminophen, 500 mg</td>
<td>3.5</td>
<td>2.7-4.8</td>
<td>61</td>
<td>32</td>
</tr>
<tr>
<td>Acetaminophen, 975-1,000 mg</td>
<td>3.6</td>
<td>3.2-4.1</td>
<td>46</td>
<td>18</td>
</tr>
</tbody>
</table>

* NNTB: Number needed to treat for benefit.

† Percentage remediating within 6 hours.

‡ Percentage remediating within 8 hours.

NSAIDs

Similar study to the one we discussed earlier re APAP users and % who exceed max recomm dose

• Authors reviewed info participants submitted via 7-day online diaries that tracked NSAID use

• 1326 participants

• Compared usage and doses with max recommended daily doses for ibuprofen OTC (1200mg) and Rx (3200mg) and ‘other’ NSAIDs

• Participants only had to enter the following information:
  • Medication they took (didn’t have to know drug was an NSAID; names were in a list)
  • When they took the medication
  • Why they took the medication

NSAIDs

Findings:

- 11% exceeded the daily limit for ibuprofen
- 4% exceeded the recommended maximum daily dose for other NSAIDs.
- Less than 40% of participants knew products listed were NSAIDs
- Only 39% of participants recognized all products taken as NSAIDs.
- Participants who took a dose THEY determined (not per product directions): > chance they exceeded max recomm daily dose

Other factors that can contribute to misuse:

• If patients exceed max SINGLE dose, more likely they will exceed max DAILY dose

• Use of multi-ingredient products NOT used for pain relief (i.e. cough/cold) along with single-ingredient products

• Use of products where single-doses COULD be more than 1 pill
  • “Gee, if the dose is 1 OR 2, I’m going to take 2 because 2 HAS to be better than 1, right?!”

NSAIDs

What can we do?

- Talk with our patients and customers about the proper use of NSAIDs
- Educate on multi-ingredient and Rx + OTC meds with similar ingredients
- Encourage people to ask questions and read/follow directions

Does the use of an NSAID in combination with either warfarin or dabigatran (for AF) increase bleeding risk?

• Post-hoc analysis of the RE-LY trial

• RE-LY: 2009 landmark trial comparing dabigatran vs. warfarin in pts with Atrial fibrillation (AF)

• 18,113 patients with AF who received either of these anticoagulants

• This analysis reviewed data for these pts to identify those who had documented use of an NSAID at least once, and to assess records to determine # who had any diagnosis related to bleeding

NSAIDs

Findings in patients taking NSAIDs PLUS an oral anticoagulant (OAC) compared with those not using an NSAID:

• Significantly higher rates of major bleeding: 5.4% (taking NSAID) vs 3.2% (no NSAID); HR, 1.68; 95% CI, 1.40 - 2.02

Risks associated with combination therapy:

• Significantly more major gastrointestinal bleeding: HR, 1.81; 95% CI, 1.35 - 2.43

• More frequent hospitalizations: HR, 1.64; 95% CI, 1.51 - 1.77

• Increased risk of stroke (primarily hemorrhagic) or systemic embolism: HR, 1.50; 95% CI, 1.12 - 2.01

NSAIDs

While appearing to be significant, authors caution these data are preliminary and there were limitations to the data:

• Patients had the ability to periodically start and stop NSAIDs

• There was a lack of data regarding the specific type of nonselective NSAID, dose, and reason for NSAID use

• Great counseling opportunity for pts receiving OAC prescriptions

**Can NSAIDs be used safely with low-dose aspirin?**

- The PRECISION trial from 2016 evaluated the potential CV risk associated with NSAID use in pts with RA or OA
- 23,953 pts: Compared celecoxib, ibuprofen, and naproxen
- **This re-eval of data from PRECISION**: compared the safety of combining NSAIDs with low-dose aspirin with data regarding NSAID use alone

**Outcomes evaluated were rates of:**

- composite major adverse cardiovascular events
- noncardiovascular death
- gastrointestinal events
- renal events
- composite endpoint

**NSAIDs**

**Findings:**

**NO Aspirin:**

- Both naproxen and ibuprofen had increased risk for the composite endpoint compared to celecoxib:
  - Naproxen HR: 1.52; 95% CI: 1.22 to 1.90, \( p < 0.001 \)
  - Ibuprofen HR: 1.81; 95% CI: 1.46 to 2.26; \( p < 0.001 \)

**Specific events:**

- Ibuprofen = more major CV events compared to celecoxib: \( p < 0.05 \)
- Ibuprofen and naproxen = more gastrointestinal (\( p < 0.001 \)) and renal (\( p < 0.05 \)) events.

**NSAIDs**

**WITH Aspirin:**

- Risk of primary composite endpoint:
  - Ibuprofen > celecoxib: (HR: 1.27; 95% CI: 1.06 to 1.51; p < 0.01);
  - Naproxen ~ celecoxib: (HR: 1.18; 95% CI: 0.98 to 1.41; p = 0.08).

**Specific events:**

- Major adverse cardiovascular events were similar among NSAIDs
- Ibuprofen > celecoxib re gastrointestinal and renal events (p < 0.05)
- Naproxen > celecoxib re gastrointestinal events (p < 0.05)

When used with ASA, celecoxib appears to be the safest NSAID of the 3 regarding overall profile

Partially based on the PRECISION trial data:

- Two FDA panels voted to include a warning on the naproxen nonprescription Drug Facts label about the interaction between aspirin and naproxen, and to make no changes to the current ibuprofen nonprescription Drug Facts label that already warns against its use with aspirin, at a joint meeting April 25, 2018.

Background information available at:

- “A Review of Naproxen/Aspirin Pharmacodynamic Interaction Data Including the Results of the Kontakt Study”
- “Regulatory History of the Interaction Between Aspirin and Other Nonprescription NSAIDs”

Status of final FDA decision and deadline for change not known.
Update on Analgesics (cont.)

Focus on back pain
Management of Back Pain - Revisited

<table>
<thead>
<tr>
<th>Education and self-care</th>
<th>Acute low back pain (&lt;6 weeks)</th>
<th>Persistent low back pain (&gt;12 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advice to remain active</td>
<td>First-line treatment, consider for routine use</td>
<td>First-line treatment, consider for routine use</td>
</tr>
<tr>
<td>Education</td>
<td>First-line treatment, consider for routine use</td>
<td>First-line treatment, consider for routine use</td>
</tr>
<tr>
<td>Superficial heat</td>
<td>Second-line or adjunctive treatment option</td>
<td>Insufficient evidence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-pharmacological therapy</th>
<th>Acute low back pain (&lt;6 weeks)</th>
<th>Persistent low back pain (&gt;12 weeks)</th>
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</thead>
<tbody>
<tr>
<td>Exercise therapy</td>
<td>Limited use in selected patients</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Cognitive behavioural therapy</td>
<td>Limited use in selected patients</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Spinal manipulation</td>
<td>Second-line or adjunctive treatment option</td>
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<tr>
<td>Massage</td>
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<tr>
<td>Acupuncture</td>
<td>Second-line or adjunctive treatment option</td>
<td>Second-line or adjunctive treatment option</td>
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<tr>
<td>Yoga</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Mindfulness-based stress reduction</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Interdisciplinary rehabilitation</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
</tbody>
</table>

| Pharmacological therapy | 
|-------------------------|----------------------------|
| Paracetamol             | Not recommended |
| Non-steroidal anti-inflammatory drugs | Second-line or adjunctive treatment option |
| Skeletal muscle relaxants | Limited use in selected patients |
| Selective serotonin reuptake inhibitors | Insufficient evidence |
| Antiseizure medications | Insufficient evidence |
| Opioids                 | Limited use in selected patients, use with caution |
| Systemic glucocorticoids | Not recommended |

| Interventional therapies | 
|--------------------------|----------------------------|
| Epidural glucocorticoid injection (for herniated disc with radiculopathy) | Not recommended |

| Surgery | 
|---------|----------------------------|
| Discectomy (for herniated disc with radiculopathy) | Insufficient evidence |
| Laminectomy (for symptomatic spinal stenosis) | Insufficient evidence |
| Spinal fusion (for non-radicular low back pain with degenerative disc findings) | Insufficient evidence |

Subacute low back pain is a transition period between acute and chronic low back pain; evidence on optimal therapies for subacute low back pain is scarce but a reasonable approach is to shift towards therapies recommended for chronic low back pain.

Table 2: Overview of interventions endorsed for non-specific low back pain in evidence-based clinical practice guidelines (Danish,* US,* and UK* guidelines)

DOI: https://doi.org/10.1016/S0140-6736(18)30489-6 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30489-6/fulltext
Management of Back Pain - Revisited

Introductory material

• Approx 80% of adults experience low back pain at some point in their lifetimes.

• 25% reported some type of low back pain in last 3 months

• Common reason for job-related disability, reduced productivity, healthcare visits, and costs (est. $100B direct and indirect)

Guideline included 3 recommendations, all related to self-care: Summary:

**Recommendation 1:** Acute or subacute low back pain:

- Most pts will improve over time regardless of treatment
- Non-pharm option(s) should be selected first
- Non-pharm option with moderate evidence: heat
- Non-pharm options with low quality evidence: massage, acupuncture, or spinal manipulation
- Pcol, if needed should include NSAIDs or skeletal muscle relaxants (moderate evidence)

**Recommendation 2:** Chronic low back pain:
Initial option should be nonpharmacologic treatment with one of the following:

- **Moderate evidence:** exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence)

- **Low evidence:** tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation

Recommendation 3: Chronic low back pain and poor response to nonpharmacologic therapy:

- Pcol options: First-line: NSAIDs
- Second-line: tramadol, duloxetine
- All: moderate evidence

Analgesic Case study

• You see an elderly female in the analgesic section of the OTC meds.
• You ask how you can assist and she states she has had aggravating, but not severe, back pain for a few days, and needs more ibuprofen.
• Upon further questioning she has been using ibuprofen periodically to help manage the pain (“And it works!”), and she ran out and is in a hurry to get home.

You obtain her name (CK) and DOB (11-26-49), and see she’s taking the following medications:

• Benazepril 10mg QD  Aspirin 81mg QD
• Atorvastatin 40mg QD  Atenolol 50mg QD
• Esomeprazole 40mg QD  Clopidogrel 75 mg QD

How would you handle this situation?
What other questions would you have?
(Think QuEST/SCHOLAR-MAC)
Update on Upper Respiratory Conditions

Focus on Asthma
Asthma Case – SP

• SP, a 25 year old IT Consultant, has recently joined his local football team
• The team coach has suggested that he seek medical advice because he is quite breathless and is having increasing difficulty keeping up with his team mates during training sessions
• SP decides to go to the pharmacy to get more information
Management of Asthma
Background Information

• Most common chronic disease among children
  • Affects 9.4% kids aged 0-17 years
  • Prevalence is higher (11.2%) in persons with incomes below 100% of poverty level
• Asthma characteristics include airflow obstruction (related to bronchospasm, edema, and mucus hypersecretion), bronchial hyperresponsiveness and airway inflammation
Pathophysiology of Asthma
Asthma Triggers
Asthma Related Deaths
• He notices that he gets a cough, shortness of breath and occasional wheeze when playing football

• He is concerned that he might have a heart condition ‘like that footballer’
  • He has no chest pain or palpitations but he does suffer from exercise-related respiratory symptoms such as cough, wheezing and a tight chest
  • He says that the only other time he has noticed any symptoms is occasionally at night, when he wakes with a tight chest

• He has a previous history of asthma as a child but this resolved when he was eight years old

• He no longer takes medication, but wants to know if the new OTC inhaler will help
Epinephrine inhalation aerosol suspension

- Approved Nov 2018

- Indicated for “temporary relief for symptoms of mild, intermittent asthma”

- For patients 12 and older with diagnosed asthma

- Uses hydrofluoroalkane (HFA) propellants instead of chlorofluorocarbon (CFC) propellants
Step-by-Step Instructions for Inhaler Use
Primatene Mist – Patient Education

Warnings: See a doctor if you
• are not better in 20 minutes
• get worse
• need more than 12 inhalations in a day
• use more than 9 inhalations a day for more than 3 days a week
• have more than 2 asthma attacks in a week

Directions for Use
• Activate inhaler before first use and clean it every day after use to prevent a medication buildup
• The inhaler needs to be shaken and sprayed once into the air before each use
American College of Chest Physicians Disagrees with FDA Decision to Approve Over-the-Counter Epinephrine for the Treatment of Asthma

November 9, 2018

Glenview, IL – The American College of Chest Physicians (CHEST) is disappointed with the FDA’s decision to approve over-the-counter epinephrine (Primatene® Mist HFA) for the treatment of asthma. CHEST is a nonprofit organization dedicated to advancing best patient outcomes. Our membership of over 19,000 members from around the world provide patient care in pulmonary, critical care, and sleep medicine.

Asthma is a serious and chronic condition with associated high healthcare burden. Care for ALL patients with asthma should be under the guidance of a health care provider. Majority of asthma patients require treatment with a controller medication, which is only available by prescription. Frequent rescue inhaler use has been associated with increased morbidity and mortality. Over the counter availability of a reliever medication like Primatene® Mist can endanger patient’s wellbeing by providing temporary relief in symptoms and resulting in delay in seeking medical care.
Exercise-Induced Asthma

Criteria for EIA

• 10% decrease in FEV1 after exercise

• $\geq 15\%$ decrease in PEFR or a FEV1 of 15% after challenge with exercise

• 10-15% decrease in FEV1 after exercise
What Do You tell SP?

- How do you advise him on this inhaler?
- What non-drug or patient education can you provide him?
Objective evidence of lung function and reversibility should be sought

Starting treatment before these tests are complete will depend on the individual

In SP’s case, home peak flow monitoring and/or an exercise tests can help to confirm the diagnosis

Response to treatment (short acting B2 agonists – SABAs) or inhaled corticosteroids (ICS) may also help to confirm the diagnosis

As SP is coming to terms with his diagnosis, he agreed to start on peak flow monitoring and a SABA
• SP’s peak flow readings confirm variability and reversibility in his lung function
• He has been getting his usual symptoms when he plays football and has responded to this by using his SABA
• He has his SABA four times a week, when he has trained and competed and he is happy that his symptoms are responding to treatment
• Reduce the chances of an attack
  • Warm-up and cool-down periods help prevent or minimize EIA episodes
  • Short-duration exercise
  • Use scarf or face mask in colder weather

• Treatment
  • Use quick relief medicines 10-15 minutes prior to activity
  • Use other medications regularly to prevent attack
  • The OTC inhaler is not preferred to a prescription drug – it should only be used in case of an emergency

• Performance
  • Inhaled B2-agonists do not improve performance
Key points – Asthma

- Asthma is a result of genetic predisposition and environmental interactions
- Primarily a chronic inflammatory disease of the airways of the lung for which there is no cure
- Inflammatory process is treated most effectively with inhaled corticosteroids
- Bronchial smooth muscle contraction is prevented or treated most effectively with inhaled B₂-adrenergic receptor agonists
- Variability in response to medications requires individualized therapy
- Ongoing patient education is essential for optimal patient outcomes and includes trigger avoidance and self-management techniques
• A 55 year old, nonsmoking patient asks the pharmacist what he can take for his cough
• He has a 3.5 week cough that started with typical URI symptoms including low-grade fever, malaise, and sore throat that progressed to rhinorrhea and eventually a dry cough
• The cough is still nonproductive, frequent and aggravated by talking
• He has been using 10-12 menthol cough drops per day for the past 2 weeks
Menthol Cough Drops: Cause for Concern?

- Regression of Cough Severity

- Y axis: ordinal 7 point scale
  - 1=very mild; 7=very severe

- X axis: Menthol dose (mg) consumed per day

J Am Board Fam Med 2018;31:183–191
Update on Gastrointestinal Self-Care

Focus on PPIs
Does the use of a short-term PPI for frequent heartburn provide benefit beyond 2 weeks?

• 2 studies assessed response to PPI up to 7 days after the last dose
• Pooled data from two identical randomized, double-blind, placebo-controlled studies.
• Pts: adults with self-reported (via diaries) frequent heartburn (≥2 days/week for 4 weeks)
• Drug regimen: Esomeprazole 20 mg qd x 14 days
• Total of 584 subjects
• Self-eval of symptom relief daily during treatment period: 0 = none; 1 = mild; 2 = moderate; 3 = severe

Results:

• All subjects in the pooled analysis set who reported diary data for at least three follow-up days were analyzed.

• Predictors of sustained symptom control during the follow-up period:
  • heartburn resolution during the last seven days of treatment BEST predictor of symptom resolution (OR 3.81, 95% CI 2.4, 6.05; p<0.0001)
  • lower incidence of heartburn frequency at baseline
  • greater number of days without heartburn during the two-week treatment period.

What does this mean?

• When discussing OTC PPI use, getting a history may help guide discussion re expected response
• Most patients will experience benefit post last-dose
• Need more research to assess response past 7-days post last dose

Does concomitant anticoagulant and PPI therapy change the risk of hospitalization due to UGI bleeding?

• Retrospective cohort analysis of Medicare beneficiaries
• Jan 2011-Sept 2015: pts who were prescribed Apixaban, dabigatran, rivaroxaban, or warfarin with or without a PPI.
• Researchers reviewed the data to determine hospitalizations for UGI bleeding in pts without and with a PPI
• Determined incidence rate ratios (IRRs).

RESULTS

• 1,643,123 pts with 1,713,183 new episodes of oral anticoagulant treatment included in the cohort
• Mean age was 76.4 years
• 651,427 person-years of follow-up
• 56.1% were for women

Anticoag WITHOUT a PPI: 754,389 treatment person-years:

The incidence for apixaban was significantly lower than:
  • dabigatran (IRR, 0.61 [95%CI, 0.52-0.70]
  • warfarin (IRR, 0.64 [95%CI, 0.57-0.73]

Anticoag WITH PPI: 264,447 person-years

• Compared to treatment without PPI:
  • Risk of UGI bleeding hospitalizations was lower overall (IRR, 0.66 [95%CI, 0.62-0.69])

• Risk of hospitalization lower when anticoag pts also receiving a PPI

• How does this relate to Self-care?
  • Pts on anticoag should NOT self-treat with a PPI
  • Recommend pts speak with their HCP about potential benefit

Researchers assessed the potential impact of PPIs on CVDz

• Systematic review and meta-analysis of the association between PPIs and cardiovascular risk, independent of clopidogrel.

• Primary outcome was association between PPI monotherapy and any adverse cardiovascular event

• secondary outcome was association between proton pump inhibitor monotherapy and acute myocardial infarction.

• Studies were excluded if they reported or did not adjust for concomitant anti-platelet therapy or involved participants aged less than 18 years.

Results

• Data from 16 studies were included in the meta-analysis (involving 447,408 participants). Of these, eight were randomised controlled trials, seven were observational studies and one was a retrospective analysis of a randomised controlled trial.

• Risk of CV event in patients using PPI monotherapy:
  • Increased risk observed using pooled data from observational studies (risk ratio 1.25, 95% CI 1.11-1.42, $I^2$ 81%, $P < 0.001$)
  • No increased risk based on data from randomised controlled trials (risk ratio 0.89, 95% CI 0.34-2.33, $I^2$ 0%, $P = 0.85$).

• **Authors conclude:** There is no clear evidence of an association between PPI monotherapy and increased cardiovascular risk.

Do PPIs increase the risk of stroke?

- Data from 2 databases were collected and analyzed:
  - Nurses' Health Study since 2000: 68,514 women (mean age, 65 ± 7 years)
  - Health Professionals Follow-up Study since 2004: 28,989 men (mean age, 69 ± 8 years)
- Reviewed medical records over a 12 year period
- The primary end point was first incident stroke.
- In the 2 cohorts, we documented 2599 incident strokes (2037 in women and 562 in men)
- Adjustment for established risk factors for stroke

Initial assessment of relationship between stroke risk and PPI use:

- significant increase in risk of ischemic stroke (hazard ratio, 1.18; 95% confidence interval, 1.02-1.37).

- Adjusting for confounding factors (such as PPI indication) stroke risk was reduced to a nonsignificant level: (hazard ratio, 1.08; 95% confidence interval, 0.91-1.27).

- Summary: regular PPI use was not associated with increased risk of stroke overall or hemorrhagic stroke.

Can PPIs decrease the serum concentrations of certain antivirals used to treat Hepatitis C?

• Systematic review and meta-analysis were completed
• Goal: determining the effects of PPIs on sustained virologic responses (SVRs) in patients with hepatitis C receiving a variety of direct-acting antivirals (DAA).
• Reminder: Goal with DAA treatment: sustained virologic response (SVR) 12 weeks following DAA therapy
• Nine cohort studies involving 32,684 pts
Results:

• Use of PPIs with DAAs: lower odds of achieving SVR compared with non-PPI users (pooled OR of 0.74, 95% CI: 0.63–0.88, p < 0.001),

• Looking specifically at SVR12: lower odds of achieving SVR12 compared with those with no use of PPI (pooled OR of 0.68, 95% CI: 0.51–0.9, p=0.01]

• Authors concluding statements: This study... “demonstrated a significantly increased risk of failure of achievement of SVR in [hepatitis C virus]–infected patients taking [direct-acting antivirals] with PPIs compared to non-PPI users. Providers should consider whether PPI therapy is indicated for these patients and withdraw PPI therapy in the absence of indications.”

Interesting note: Reviewing PIs for DAAs: there is information regarding potential drug interactions with PPIs.

Specifically:

- Label for ledipasvir/sofosbuvir states that the solubility of ledipasvir decreases as gastric pH increases (so concern not just with PPIs). The label recommends that doses comparable to omeprazole 20 mg or lower can be administered simultaneously with the drug under fasting conditions.

- The mfr of sofosbuvir/velpatasvir recommends separating admin by 4 hrs if PPI is medically necessary

- But what about OTC PPIs? H2RAs?

GI Case Study

• You see a male in the GI section of the OTC meds.
• You ask how you can assist and he states he has heartburn and saw a commercial for a brand name PPI that he wants to purchase.
• Upon further questioning he has been using various antacids for a week or so with some relief.

DOB (7-14-74); he’s taking the following medications:
• Lisinopril 10mg QD   Eliquis 5 mg BID
• Atorvastatin 20mg QD   Amiodarone 100 mg BID
• Loratadine 10 mg BID   Famotidine 10mg OTC PRN

How would you handle this situation?
What other questions would you have?
(Think QuEST/SCHOLAR-MAC)
Legislative Update

Focus on Naloxone
Naloxone Access in Community Pharmacies

Based on data collected by NASPA (updated January 2019)

[Map of the United States showing different access levels for naloxone in each state.]

Legend:
- Statewide Protocol/Pharmacist Prescribing
- Statewide Standing Order
- Dispense without a prescription
- Standing Order
- None
Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths

• FDA developed a model DFL with easy-to-understand pictograms on how to use the drug
  • Nasal spray
  • Auto-injector

• FDA also conducted label comprehension testing to ensure the instructions were simple to follow

• This is the first time FDA has proactively developed and tested a DFL

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629571.htm
Drug Facts Label
Miscellaneous Self-Care Information
More evidence to support the need to ask about OTC med use

- Charts of pts admitted to a cardiology service were reviewed
- 3-month period March – May 2016
- Inclusion: 404 pts ≥ 65 years of age, history of CVDz, taking at least 1 OTC med at home (per medical record)
Miscellaneous Self-Care Information

Results:
• 281 (69.6%) taking at least 1 OTC
• Ave: 2.35 ± 1.57 products per pt
• Range: 1-9

Most common categories:
• Vitamins: 37.3%
• Laxatives: 17%
• Minerals: 13.6%
• Stomach acid reducers: 9%
• Analgesics: 3.6%

Miscellaneous Self-Care Information

Other demographics OTC users:
• More comorbidities
• More Rx meds
• Dx of A Fib, sleep apnea, GERD

What can we do?
• Assume pts ARE taking an OTC product
• Ask pts receiving CV meds about OTC med use
• Remind pts of potential benefits and harm/risks

Miscellaneous Self-Care Information

• The National Association of Chain Drug Stores (NACDS) Foundation hosted a forum Oct 2016, recommended action steps Forum results just recently published in JAPhA

• How do pharmacies document and access information regarding OTC med use and purchases by patients/caregivers?

• Integration into EHRs? Complex process

• Goal of the forum: Develop recommendations to improve the documentation of OTC medication use by patients.

Miscellaneous Self-Care Information

Challenges:

• How should OTC meds be identified? NDC, UPC, other?
• Documentation/reporting in dispensing systems, and link to alert software
• Multiple retailers: 750K+
• Who buys vs who uses?
• Privacy/confidentiality

Miscellaneous Self-Care Information

Miscellaneous Self-Care Information

• A report released by National Council on Patient Information and Education (NCPIE) focuses on the importance of self-care

• Empowering Americans to Take Greater Responsibility for Their Health: A Roadmap for Building a National Self-Care Movement in the U.S

• Highlights key statistics that support more movement in the area of self-care:
  • Aging population
  • Greater role of minor and chronic diseases
  • Healthcare spending exceeds $3 Trillion annually
  • Growth of consumer use of technology (web, wearables, self-monitoring)
  • Up to 50 million visits to primary care physicians annually could be avoided
  • Possible economic benefit: > $5 billion per year
  • Self-care is one of the IOM’s 4 pillars of healthcare

Ref: http://www.bemedwise.org/docs/resources/2018ncpie_selfcarereport_0.pdf
Assessment Question #1

Adapalene, the first nonprescription topical retinoid, has which acne fighting property that is different from benzoyl peroxide?

a. Antibacterial  
b. Anti-inflammatory  
c. Comedolytic  
d. Keratolytic
Assessment Question #2

In the study evaluating whether certain acetaminophen product strengths could lead to excessive dosing:

a. Users taking the 325mg strength tablet had a greater chance of exceeding 4 grams/day

b. Users who did exceed 4 grams per day of acetaminophen took an average of 5.2 grams/day

c. Users taking the 650 mg strength tablet were more likely to know the correct dosing interval

d. Regardless of the product strength a majority of acetaminophen users were likely to exceed the maximum recommended daily dose of 4 grams/day
Which patient situation would be most appropriate for recommending an OTC epinephrine inhaler?

a. Reports no longer having a prescriber
b. Wakes nightly due to coughing/wheezing
c. Needs a prescription albuterol but it’s too soon
d. Left albuterol inhaler at home while on vacation
Assessment Question #4

Which of the following is the best predictor of sustained heartburn relief with the use of a PPI?

a. Symptom resolution within the first 3 days of therapy
b. Increased frequency of heartburn symptoms at baseline
c. Greater number of days without heartburn symptoms during treatment
d. The dose of PPI taken
Closing remarks/conclusion