Peds and OTC: Little Ones, Little Doses
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Objectives
- Review available OTC products for commonly encountered pediatric disease states
- Discuss new restrictions and labeling requirements for OTC pediatric products
- Calculate correct dosages for OTC medications based on pediatric patient parameters
- Recognize contraindications and adverse effects of available pediatric OTC therapies

Peds vs. Adults:

<table>
<thead>
<tr>
<th>Absorption</th>
<th>PO: Slower gastric emptying</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Topical: Greater systemic absorption</td>
</tr>
<tr>
<td></td>
<td>Rectal: best when lipid soluble</td>
</tr>
<tr>
<td>Distribution</td>
<td>% body water decreases with age</td>
</tr>
<tr>
<td></td>
<td>% body fat increases with age</td>
</tr>
<tr>
<td>Metabolism</td>
<td>Low glucuronidation</td>
</tr>
<tr>
<td></td>
<td>Low alcohol dehydrogenase</td>
</tr>
<tr>
<td>Elimination</td>
<td>Lower compared to adults</td>
</tr>
</tbody>
</table>

Common Sources of Medication Errors in Pediatrics

- Dosage Errors
  - Calculation Errors
    - Incorrect weight (lbs vs. kg)
    - Mg/kg/day vs. mg/kg/dose
- Transcription Errors
- Formulation Errors

Dosing Directions

2009 FDA guidelines in response to unintentional overdoses
- All OTC liquid drug products should include a measuring device
- Device and directions should use same abbreviations and units of measurement
- Devices should bear only necessary markings
- Devices should not hold significantly more than largest dose
- Abbreviations should conform to standards
- Decimals and fractions should be used with care
- Studies should be done to confirm accurate use

2010 study to determine prevalence of inconsistent dosing directions
- Design: top 200 pediatric oral liquid OTC medications
- Outcome measures:
  - Inclusion of measuring device
  - Inconsistency between directions and measuring device
  - Use of nonstandard units and abbreviations
  - Presence of abbreviation definitions
Results

- Measuring devices included with 74% of products
- Inconsistencies found in 98.6%
  - Missing markings (24.3%)
  - Superfluous markings (81.1%)
- Nonstandard abbreviations used by 97 products
- No definition of abbreviations in 163 products

Fever: When to Refer to Physician

- > 6 mo old with rectal temp ≥ 104°F (40°C)
- < 6 mo old with rectal temp ≥ 101°F (38°C)
- History of seizures/ febrile seizures
- Fever persists >3 days with/without treatment
- Development of spots/ rash
- Refusing to drink or cannot hold down fluids
- Very sleepy, irritable or hard to wake up

Fever/ Pain Treatment Options

<table>
<thead>
<tr>
<th>Drug</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Acetaminophen | >2 years old  
               | 10-15 mg/kg                 |
| Ibuprofen  | >2 years old  
               | 7.5 mg/kg  
               | Max 1200 mg/day             |
| Naproxen   | >12 years old  
               | 220- 440mg, then 220mg Q8-12h  
               | Max 660 mg/day              |

Acetaminophen Concentration

- Now single concentration of 160mg/5ml for all OTC APAP products
- Both infants’ and children’s product same concentration
- Dosing recommendations have NOT changed

APAP Enhanced Dosing Directions

- FDA Advisory Panel recommends enhanced dosing directions
- Single-ingredient pediatric APAP
- Will include dosing directions for children 6-23 months old
- Weight-based and age-related dosing
- For now, still need PCP instructions
Cough, Cold, Allergies

- More than 60% of OTC recommendations involved cough and cold products
- Common cold is leading cause of missed school days
- From 1969 to 2006, more than 120 pediatric deaths related to cough and cold products


Cough/Cold: When to Refer to Physician

- Fever > 101.5°F (38.6°C)
- Infants < 9 mo of age
- Worsening of symptoms during self treatment
- Cough with thick yellow sputum or green phlegm
- Drenching nighttime sweats


Cough/Cold: Treatment Options

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Usual Dosage</th>
<th>Max Dosage</th>
<th>ADRs related to excessive doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brompheniramine</td>
<td>2-6y: 1mg Q4-6 6-12 y: 2mg Q4-6</td>
<td>2-6y: 5mg Q4-12 6-12 y: 12mg/24 h</td>
<td>Palpitations, paradoxical excitability</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>2-6y: 5mg ≥ 6 y: 10mg</td>
<td>2-6y: 5mg/24 h ≥ 6 y: 10mg/24 h</td>
<td>Hypertension, tachycardia, chest pain</td>
</tr>
<tr>
<td>Phenylephrine</td>
<td>2-6y: 5mg ≥ 6 y: 10mg</td>
<td>2-6y: 5mg/24 h ≥ 6 y: 10mg/24 h</td>
<td>Hypertension, angina, retrobulbar, peripheral vasoconstriction</td>
</tr>
<tr>
<td>Dextromethorphan</td>
<td>2-6y: 5mg ≥ 6 y: 10mg</td>
<td>2-6y: 5mg/24 h ≥ 6 y: 10mg/24 h</td>
<td>Confusion, dysarthria, stupor, nystagmus, dystonia, coma, seizures</td>
</tr>
<tr>
<td>Guaifenesin</td>
<td>2-6y: 5mg ≥ 6 y: 10mg</td>
<td>2-6y: 5mg/24 h ≥ 6 y: 10mg/24 h</td>
<td>Nausea, vomiting, dizziness, nephrolithiasis</td>
</tr>
</tbody>
</table>


Cough/Cold: FDA Recommendations

- 2008 Public Advisory: OTC cold medications should not be given to children < 2yo because of lack of efficacy and high risk for adverse events and death
Allergic Rhinitis

- A systemic disease with prominent nasal symptoms
- An estimated 40% of children in the US have this disease
- Treatment steps:
  - Allergen avoidance
  - Pharmacotherapy
  - Immunotherapy

Allergy: When to Refer to Physician

- Children <12yo
  - Unless already diagnosed by PCP and approved for OTC treatment
- Symptoms of otitis media, sinusitis, bronchitis, or other infection
- Symptoms of undiagnosed asthma
- Symptoms unresponsive to treatment

Allergy: Treatment Options

- Loratadine (Claritin®)
- Cetirizine (Zyrtec®)
- Fexofenadine (Allegra®)
- Intranasal Cromolyn (NasalCrom®)
  - More effective if started before symptoms begin
- Diphenhydramine (Benadryl®)
  - Should be avoided due to paradoxical excitation

GI Diseases

Nausea/Vomiting

- Commonly caused by viral gastroenteritis
  - Rotavirus and norovirus
- May lead to dehydration
- Treatment is directed at preventing and correcting dehydration and electrolyte disturbances

Nausea/Vomiting: When to Refer to Physician

- S/S of severe dehydration
- Stiff neck
- <6 mo or <8 kg, vomited clear fluids 3 times
- Refusal to drink
- Lack of urination in past 8-12 hrs
- Vomiting with each feeding
- Vomitus contains red, black, green fluid
Nausea/Vomiting: Treatment Options

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dosage (Max Daily Dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimenhydrinate (Dramamine®)</td>
<td>12.5-25 mg Q 6-8 hrs (75 mg)</td>
</tr>
<tr>
<td>Calcium Carbonate (Children’s Pepto®)</td>
<td>1 tablet (161mg), repeat (3 tablets)</td>
</tr>
<tr>
<td>Phosphorated carbohydrate solution (Emetrol®)</td>
<td>5 to 10 ml Q 15 min (1hr, 5 doses)</td>
</tr>
</tbody>
</table>

Diarrhea

Each year, acute gastroenteritis associated with diarrhea accounts for:

- 1.5 million outpatient visits
- 200,000 hospitalizations
- ~300 deaths

Diarrhea: When to Refer to Physician

- <6 mo of age
- Severe dehydration
- >6 months with persistent high fever
- Blood, mucus or pus in the stool
- Protracted vomiting
- Severe abdominal pain/distress
- Inability of caregiver to administer ORT

Diarrhea: Treatment Options

<table>
<thead>
<tr>
<th>Children 6-8 years (48-59 lbs)</th>
<th>Children 9-11 years (60 -95 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loperamide (Imodium®)</td>
<td>2 mg initially, then 1mg after each loose stool. Max 4mg/ 24 hrs</td>
</tr>
<tr>
<td></td>
<td>2 mg initially, then 1 mg after each loose stool. Max 6mg/ 24 hrs</td>
</tr>
</tbody>
</table>

Dehydration

- Dry mouth and tongue
- Sunken and/or dry eyes
- Sunken fontanel
- Decreased urine output
- Dark urine
- Fast heartbeat
- Thirst
- Absence of tears when crying
- Decreased skin turgor
- Unusual listlessness/sleepiness
- Weight loss

Dehydration: Treatment Options

- Oral rehydration solution (ORS) is preferred treatment
- Give 1-2 tsp every 1-2 min if needed
- Premixed solutions are preferred
- 50-100 ml/kg over 3-4 hours
- 10 ml/kg for each loose stool
- Continue 4-6 hrs Resume feeding
**Constipation**

- May be described as:
  - Straining to have a stool
  - Passage of hard, dry stool
  - Passage of small stools
  - Feelings of incomplete bowel evacuation
  - Bloating or decreased stool frequency

**Constipation: When to Refer to Physician**

- Significant distention or cramping
- Fever
- Daily laxative use
- Blood in stool, or dark/tarry stool
- Change in character of stool
  - (i.e., becomes pencil thin)
- Bowel symptoms persist > 2 weeks

**Constipation: Treatment Options**

- Glycerin suppositories
  - Onset within 15-60 minutes
- Barley malt extract
  - Safe for infants younger than 2 months
- Avoid:
  - Mineral oil (aspiration risk)
  - Stimulant laxatives (dehydration risk)

**Teething**

- Mild pain, irritation, reddening, excessive drooling
- Eruption cysts: bluish, soft, round
- Goals:
  - Relieve gum pain and irritation
  - Reducing child’s irritability
  - Reducing sleep disturbances

**Teething: Treatment Options**

- Benzocaine 5-10% (Baby Orajel®)
  - Benzocaine 20% too potent for infants
  - Beware of hypersensitivity
  - Gels are best choice
  - No more than 4 times a day
- Phenol 0.5% (Anbesol®)
  - Not currently marketed for teething pain

**Diaper Dermatitis**

- Commonly known as diaper rash
- Most common dermatologic disorder of infancy
- Caused by a combination of factors
- Goals:
  - Relief of symptoms
  - Prevent recurrences
  - Prevent secondary infection
Diaper Dermatitis: When to Refer to Physician

- Lesions present > 7 days
- Secondary infection
- Dermatitis outside of diaper region
- Broken skin due to disease progression
- Oozing, blood vesicles, or pus
- Constitutional symptoms
  - Fever, diarrhea, vomiting, swollen lymph nodes

Diaper Dermatitis: Treatment Options

- Zinc Oxide
- Calamine
  - Mixture of zinc and ferrous oxides
- Petrolatum
- Dimethicone
  - Repels water, soothes and counteracts inflammation
- Lanolin
  - Bacteriostatic, hypoallergenic
- Topical cornstarch
  - Warning against inhalation of powder

Review Questions

- True or False:
  - Acetaminophen will no longer be produced in concentrated infant drops. Liquid acetaminophen products for children under 12 will be sold as a 160 mg/5ml concentration.
  - The drug of choice for an 8 year old child presenting with a fever is a baby aspirin
  - When used for teething pain, topical benzocaine (10%) may be used up to 4 times daily

Patient Case:

“We really need your advice!”
Concerned parents state that their 3 year old daughter has felt warm and is not eating well.

Patient Case

- What questions would you ask?
- What would you recommend?
  1. Refer for medical attention
  2. Monitor symptoms and fever and recommend nondrug measures only
  3. Recommend a medication alone or combined with nondrug measures
  4. Make no recommendations
- Any additional patient education?

Conclusion

- Always take a complete history when advising on pediatric OTC medications
- Stay informed about new products and dosage recommendations
- Know when to say NO!