

Protecting Access to Pain Relief (PAPR) Coalition FDA Workshop Presentation

November 15, 2024

Conflict of Interest



I have no conflicts of interest

Coalition's History

- **The Coalition was formed** in response to the FDA's January 2014 announcement that it intended to limit access to OTC acetaminophen (above 325 mg), which could compromise the health of individuals living in pain.
- **Officially launched on July 22, 2015**
 - **Press Release:** Covered by major news outlets (Businesswire and Reuters)
 - **Website went live:** <http://www.paprcoalition.com/>
- **The Coalition's Mission** is to support continued access to and choice of appropriate over-the-counter (OTC) pain relief. The Coalition accomplishes its mission by supporting evidence-based education on safe use of OTC pain relief options as a part of a patient consumer's comprehensive pain management plan developed with their health care provider.

American Society for Pain Management Nursing (ASPMN)



MISSION STATEMENT AND GOALS

The mission of the American Society for Pain Management Nursing is to support integrative, whole person, evidence-based care to all those experiencing pain. This shall be accomplished through collaborative and inter-professional partnerships, education, research and advocacy.

Lessons Learned: Challenges with Aged Based Dosing

- **Different levels of physical development**
- **Confusion from one child to another in families**

Lessons Learned: Weight Based Dosing

- **More accurate**
- **Easier to understand**
- **Younger children in the household**
- **But – Does everyone have a scale?**

Lessons Learned

- **Acetaminophen and NSAIDS – backbone of pain management**
- **Low Medical Literacy**
- **Labeling not just on the packaging – The bottle too**
- **OTC Challenges with those not proficient in English**

Role of Packaging and Labeling

- **In-patient (healthcare provider controlled)**
- **Out-patient (parent/caregiver controlled)**
- **Difficulty understanding dosing**
- **Drug Facts Label**
- **Active Ingredient – Prominently Displayed**

Dosing

- **Post surgery – Stronger medications dosing is clearer**
- **Different dosing intervals**
 - **Creates confusion in combination medication**
 - **Cannot dose differently**
 - **Medications wearing off – Not good pain management**

Post-Op Medicine Chart



PLACE PATIENT STICKER HERE		Post-Op Medicine Chart: Please use this table to write down when medicine is given.	
	1	2	
	Give _____ mL of acetaminophen (also called Children's Tylenol 160mg/5mL) every 6 hours <i>as needed</i> for <i>mild to moderate</i> pain.	May rotate with _____ mL of Children's Motrin (Children's Ibuprofen 100mg/5 mL) every 6 hours <i>as needed</i> for <i>mild to moderate</i> pain if not controlled with acetaminophen/Tylenol alone.	
	Acetaminophen/Tylenol	Ibuprofen/Motrin	
Day 1	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	
Day 2	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	
Day 3	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	
Day 4	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	
Day 5	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	
Day 6	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	
Day 7	1. _____ 3. _____ 2. _____ 4. _____	1. _____ 3. _____ 2. _____ 4. _____	

For Questions:
 WEEKDAYS BETWEEN 8:30 A.M.- 4:00 P.M., CALL THE ENT CLINIC NURSE TRIAGE LINE: 614-722-6547
 AFTER 4:00 P.M. WEEKDAYS OR ON WEEKENDS, CALL 614-722-2000, ASK FOR "ENT DOCTOR ON-CALL"

Dosing Types

- **Delivery mechanisms**
 - **Liquid – measurement, flavor, and volume issues**
 - **Orally Disintegrating Tablets**
 - **Concentrated medications - Less is better**
 - **Topical**
 - **Patches**
- **Consider those who are:**
 - **Medication refusers, or have**
 - **Cognitive/Developmental Delays**

Final Thoughts

- **Avoid Confusion and Guessing**
- **Educate Healthcare providers (especially nurses) on any new OTC medications**

Room for Error is MUCH Smaller with Children

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Thank you