

Impact of Candy-Like Characteristics on Medication Adherence in Pediatric Populations

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Disclosures

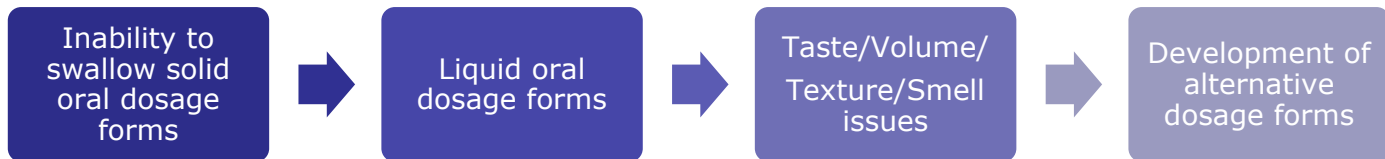
- Consultant: CMP Pharma, Wolters Kluwer

Objectives

- Illustrate the need for alternative dosage forms in children
- List potential toxicities with multivitamin overdoses in children
- Propose a definition of “candy-like”
- Discuss opportunities to improve adherence in children with non-candy-like dosage forms

Administering Medicines to Kids... Out in the Wild!!!

- Administering medication to children is difficult for multiple reasons



What's on the Market in the US?



Keep Compounding Pharmacies in Mind...

- From the website of a compounding pharmacy:
 - "Common dental compounds:
 - Chloral hydrate gummy squares, flavored
 - Hydroxyzine gummy squares, flavored"
 - Chloral hydrate is no longer commercially available in the US
 - High risk of respiratory depression, re-sedation after discharge
 - Narrow therapeutic index, high risk in overdoses (ventricular dysrhythmias, hypotension)

Risks with “Candy-Like” Medicines

- Overdose
 - Make it too much like candy and the risk of kids taking too much increases
- Sugar content
 - 1-3.5 g of sugar per gummy
 - Some products have a dose of 2 gummies (thus doubling the sugar dose)
 - Provides up to 10% of the RDA for sugar
 - Risk for dental carries
 - *Remember that most gummies are daily multivitamins*
- Ingredient consistency
 - Gummies are not as stable as tablets/capsules, thus ensuring correct ingredient amounts is more difficult

Overdose Risks

- Iron
 - Acute toxicity when large amounts of vitamins are consumed at once
 - Doses of >60 mg/kg can result in severe toxicity

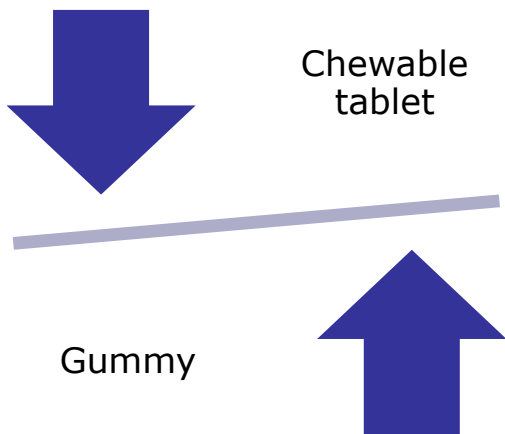
- Calcium
 - In overdoses can cause gastrointestinal symptoms and cardiac dysrhythmias

Overdose Risks

- Case report of a 20-month-old girl with chronic overdose of "L'il Critters" calcium and Vitamin D3 gummy vitamins
 - Mother administered multiple times per day for several weeks or even months
 - Severe case of child neglect
 - Labs:
 - Calcium = 20.7 mg/dL
 - Ionized calcium = 2.5 mmol/L
 - QT shortened at 252 milliseconds
 - *"This case emphasizes the dangers of gummy dietary supplements in a unique manifestation of medical neglect"*

What are the alternatives?

- Chewable tablets
- Liquid
- ***There are no USP verified non-chewable tablet multivitamins for children on the market (that I have been able to find)***



What if we simply create a solid dosage form that kids can swallow?

Why does it have to be “Candy-Like” for kids to take it?

Can children swallow tablets? Yes!

- Children as young as 2 days old have been shown to swallow mini tablets
- Children as young as 4 years capable of swallowing tablets of varying sizes (6, 8, 10 mm)

What should “Candy-Like” be defined as?

- Define the sugar content
 - 1 gram or greater per dose unit (i.e. individual gummy) = Candy
- Other thoughts
 - Development of other solid oral dosage forms for children
 - Kids can swallow tablets!
 - Encourage consumers to choose products that have ingredient quantities verified by third parties such as USP

Conclusion

- There is a delicate balance between making medications "acceptable" and "desirable"
- Limits on sugar content would be helpful
- Child-safety packaging is a MUST
- Clear directions about correct dosing and dose limits is imperative

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