Changes to Existing Product Characteristics – The Pharmacist Prospective

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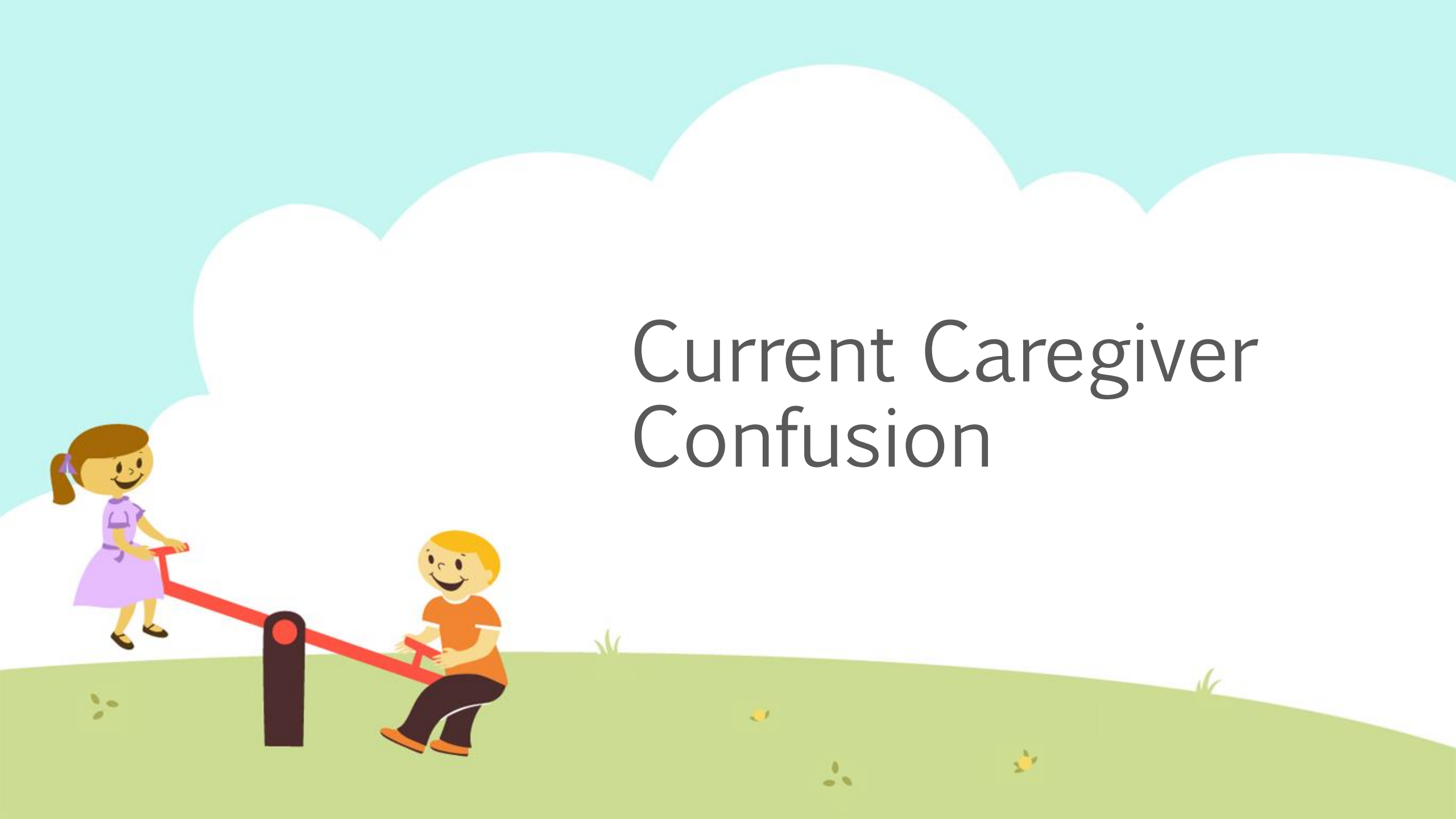
Disclosures

- Consultant for
  - Baxter
  - BBraun/CAPS
  - Fresenius Kabi
  - Wolters-Kluwer

Learning Objective

- Discuss the practical needs for extensive communication and education prior to changes in existing product characteristics

Current Caregiver Confusion



Ibuprofen

- Currently, two products on the market
  - Infant ibuprofen (40 mg/mL)
  - Children's ibuprofen (20 mg/mL)
- Many parents do not recognize difference between products

Real World Example

- Caregiver sent to obtain ibuprofen for infant
- Store does not have infant ibuprofen available so purchasing children's ibuprofen
- Caregiver asks pharmacist about children's ibuprofen
- Despite discussion with pharmacist, caregiver continues to state, "I give the same 'x mL' as I always do?"

Other Possibilities . . .

- Confusion between concentration differences when family has two children, and healthcare provider recommends
  - Infant ibuprofen for the 9-month-old infant (6.5 kg)
  - Children's ibuprofen for the 3-year-old child (14.5 kg)
- Does the caregiver grab correct product when administering dose to each child?

Education is available!

How to give the right amount of IBUPROFEN (also known as Motrin, Advil) is different depending on which type of ibuprofen you plan to give.

Dose: Give every 6 hours if needed, for fever or pain. **DO NOT GIVE MORE THAN 4 DOSES IN 24 HOURS.** Do **NOT** use with any other medicine containing ibuprofen.

Weight	Age	Infant's Ibuprofen Drops (50 mg / 1.25 mL)	Children's Liquid Ibuprofen (100 mg / 5 mL)	Children's Ibuprofen Chewable Tablets (100 mg)	Adult's Ibuprofen Tablets (200 mg)
0 to 11 pounds (up to 5 kilograms)	**0 to 5 months**	———	———	———	———
12 to 17 pounds (about 6 to 7 kilograms)	**6 to 11 months**	1.25 mL	2.5 mL*	———	———
18 to 23 pounds (about 8 to 10 kilograms)	**12 to 23 months**	1.875 mL	4 mL*	———	———
24 to 35 pounds (about 11 to 15 kilograms)	**2 to 3 years**	2.5 mL	5 mL*	1 tablet	———
36 to 47 pounds (about 16 to 21 kilograms)	**4 to 5 years**	3.75 mL	7.5 mL*	1 ½ tablets	———
48 to 59 pounds (about 22 to 26 kilograms)	**6 to 8 years**	5 mL	10 mL*	2 tablets	1 tablet

***Note:** This dosage is for **children's liquid ibuprofen** products given by dropper. See the previous column for correct dose-by-weight for **infant ibuprofen drops**, which are more concentrated.

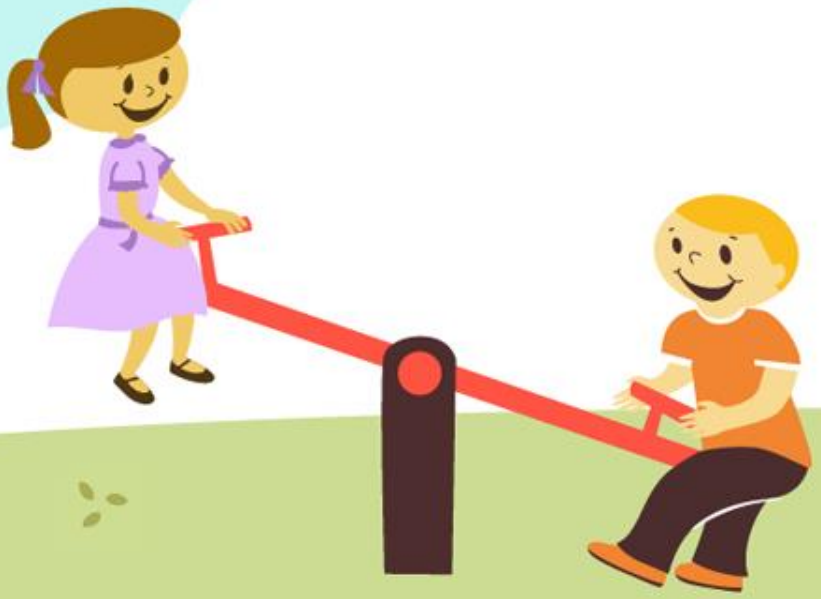
https://www.healthychildren.org/English/safety-prevention/at-home/medication-safety/Pages/Ibuprofen-for-Fever-and-Pain.aspx

What Could Happen?

- Based on dosing recommendations
  - 9-month-old infant (6.5 kg) = 1.25 mL = 50 mg (~ 7.7 mg/kg/dose)
  - 3-year-old child (14.5 kg) = 5 mL = 100 mg (~ 6.9 mg/kg/dose)
- If dose in mL recommended for patients with correct products but
  - Use infant product for both (40 mg/mL)
    - 9-month-old infant (6.5 kg) = 1.25 mL = 50 mg (correct dose)
    - 3-year-old child (14.5 kg) = 5 mL = 200 mg (~ 13.8 mg/kg/dose – OVERDOSE)
  - Use children's product for both (20 mg/mL)
    - 9-month-old infant (6.5 kg) = 1.25 mL = 25 mg (~ 3.8 mg/kg/dose – UNDERDOSE)
    - 3-year-old child (14.5 kg) = 5 mL = 100 mg (correct dose)

Change in Product Requires Extensive Education

Acetaminophen Example



Acetaminophen Before 2011

- Like ibuprofen, currently, acetaminophen also consisted of two concentrations prior to 2011
  - Infant acetaminophen (100 mg/mL)
  - Children's acetaminophen (32 mg/mL)
- Recommendation after 2009 FDA meeting to go to one concentration to avoid caregiver confusion and concerns for unintentional overdoses
- Consumer Healthcare Products Association (CHPA) decision to go to universal concentration of 32 mg/mL in 2011

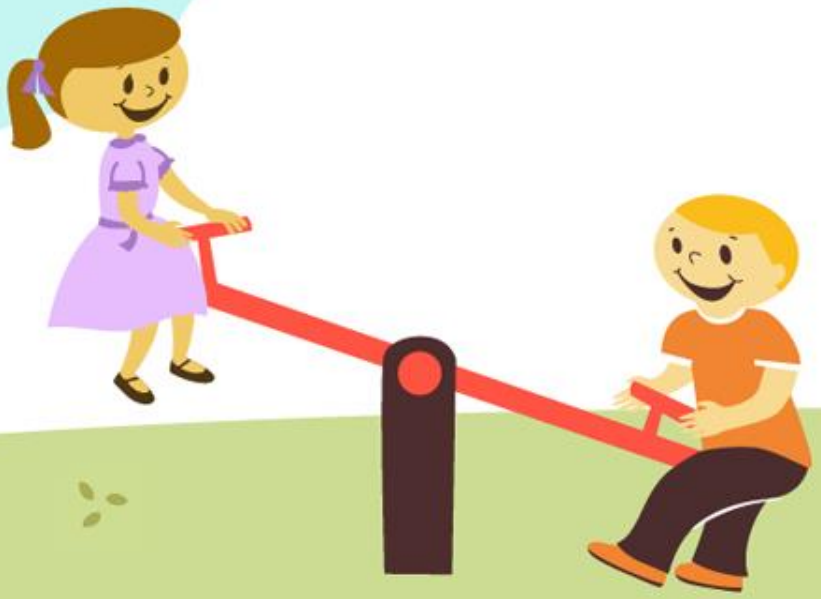
Acetaminophen Education and Guidance

- FDA education to caregivers in December 2011
  - https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-important-change-concentration-over-counter-otc-liquid-acetaminophen-marketed
- FDA OTC Pediatric Oral Liquid Drug Products Containing Acetaminophen – Guidance for Industry in August 2015
  - https://www.fda.gov/media/89475/download

FDA Acetaminophen – Guidance for Industry

- Only 32 mg/mL concentration (160 mg/5 mL)
- Clear labeling on package
  - Concentration “160 mg/5 mL”
  - Age range and units of age
  - Dosing directions only in mL
  - Image of dosage delivery device
- Appropriate dosage delivery device
  - Included with product and marked in mL

Concerns for Improper Dosing



Incorrect Use of Dosing Devices

- Yin HS, Mendelsohn AL, Wolf MS, et al. *Arch Pediatr Adolesc Med*. 2010;164(2):181-186.
  - Objective: To assess parents' administration errors by dosing instruct type and exam degree to which parents' health literature influences dosing accuracy
  - Dosing within 20% of recommended dose:
    - Cup with printed markings = 30.5%
    - Cup with etched markings = 50.2%
    - Dropper, dosing spoon, oral syringe = > 85%
- Williams TA, Wolf MS, Parker RM, et al. J Pediatr. 2019;215:244-251.e1
  - Further assessment of health literacy perspective

. . . But Education Can Make a Difference

- McMahon SR, Rimsza ME, Bay RC. *Pediatrics*. 1997; 100 (3): 330–333.
  - Objective: To determine whether parental errors in dosing liquid medication can be decreased through education
  - Intervention
    - Group 1 = Prescription and verbal instructions
    - Group 2 = Prescription, syringe, and correct dose demonstrated
    - Group 3 = Prescription, correct dose marked syringe, and demonstration
  - Results for correct dosing
    - Group 1 = 37%
    - Group 2 = 83%
    - Group 3 = 100%
    - At 1 month follow-up, 23 of 26 still demonstrated correct dose

Again, Education is Available!

How to Use Liquid Medicine for Children

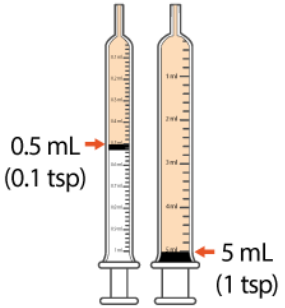
How to measure liquid medicines

- Use the dropper, syringe, medicine cup or dosing spoon that comes with the medicine. If the medicine does not come with a dosing tool, ask your pharmacist or doctor for one. Never use teaspoons, tablespoons or other household spoons to measure medicine.

  - Be sure to use a dosing tool that is just right to fit the dose you want to measure. The tool should not be too big, or too small. Using a dosing tool that is too big makes it easy to give too much medicine. Using a dosing tool that is too small means having to measure more than one time to give the right amount. This makes it easier to give the wrong amount.

- Medicine can be measured in different ways. You may see teaspoon (tsp), tablespoon (tbsp or TBSP), or milliliters (mL, ml, or mLs) on the dosing tool. **It is easier to measure the right amount with a dosing tool that uses milliliters (mL).**

- Look very carefully at **how the dose amount is written**. Be especially careful if you see a period (".") in the middle of the number. For example, "0.5 mL" is not the same as "5 mL". Mixing these up can mean giving 10 times more medicine than your child needs. Or it may mean giving your child 10 times less medicine.

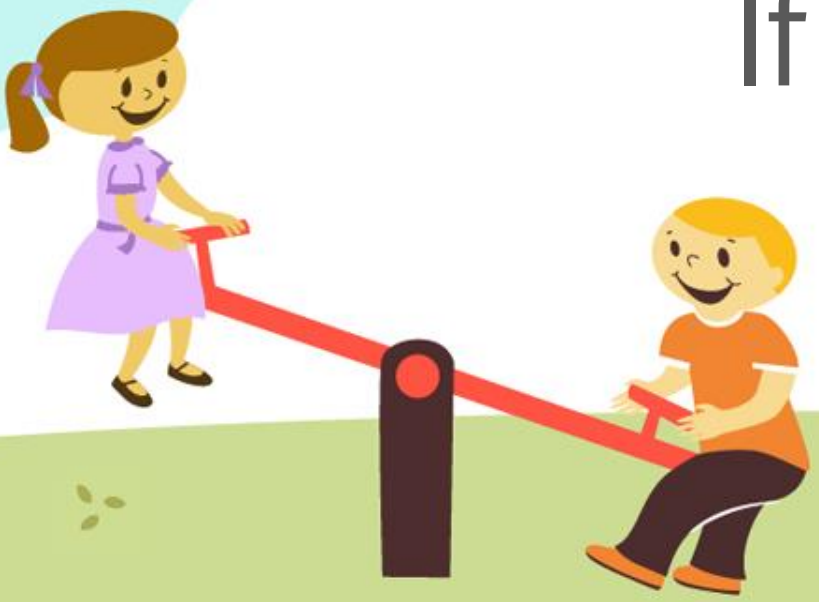


- If you are not sure how much medicine to give your child, talk wiht your doctor or a pharmacist.
  - Ask your doctor or pharmacist to **show you** how much medicine to give using the tool you plan to use at home.
  - Tell your doctor or pharmacist how much you plan to give, or use your tool to point to how much you plan to give. Then **ask if what you said is correct**.
  - Ask your doctor or pharmacist to **write down the instructions on a piece of paper** for you to take home.
  - Ask the doctor or pharmacist to **give you information in the language you prefer**, if possible. Having an interpreter help give you instructions, and having information written down in the language you prefer, means that you will be less likely to make an error.
  - **Don't hesitate to ask questions.** Many people feel confused by medicine instructions. If you are uncertain how to give your child a medicine, it is always better to ask questions than to give the medicine incorrectly.

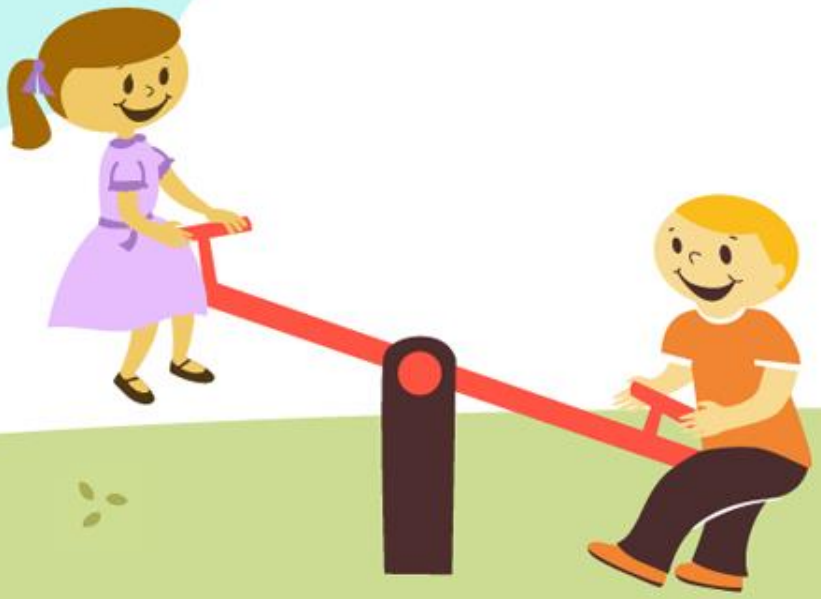
- Keep your dosing tool with your medicine so that it is easy to remember to use them together. Keep them up and away, and out of sight of young children. That way they won't get into them when you are not watching.

https://www.healthychildren.org/English/safety-prevention/at-home/medication-safety/Pages/Using-Liquid-Medicines.aspx

If changes are made . . .



Communication and education will be essential!



Questions?

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