



Module 3

Theory material 1:

Principles of pediatric medication administration

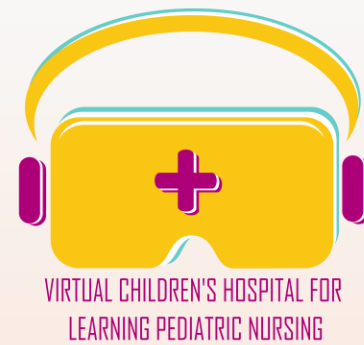


VIRTUAL CHILDREN'S HOSPITAL FOR
LEARNING PEDIATRIC NURSING

Background

- From 29% to 84% of children aged 0–18 years use prescription or over-the-counter medicines
- The most commonly used prescription medicines in all age groups of children are medicines for respiratory conditions, antimicrobials, antihistamines and skin creams
- Among over-the-counter medicines, painkillers, cough medicines and cold medicines are the most commonly used
- In addition, most of the small children receive vitamin D, and preschool-aged multivitamin and micronutrient supplements.

Special features and problems of children's medicines



Children are often treated with medicines that do not have indications for pediatric patients (= off-label medication)

- limited data pertaining to the dosing, efficacy, and safety of medications in children
- the formulation of the medicine makes it difficult to administer small dosages accurately or the formulation is not suitable for the child
- Severe side effects that are not known in adults
- Medicines meant for adults may contain unsuitable or even harmful supplements, preservatives, additives or solvents (e.g. alcohol)



- A child's illness may differ from that of an adult, requiring a different dose or medication. A child may also be more or less sensitive to the side effects of medication than an adult.
- Children do not want to take medicine (difficult to swallow, bad taste etc.)
- Children's growth and developmental changes affect absorption, distribution, metabolism and excretion of the medicine



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Absorption

- Gastrointestinal function differs from adults' GI function
 - Intestinal transit time is shorter in young children which may reduce the amount of drug absorbed
 - Gastric pH decreases during infancy to reach adult values by two years of age. The impact of these differences in gastric pH can be significant for absorption of orally administered drugs.
- Greater permeability of the skin and larger surface area of the skin
 - topically administered medications have greater potential for absorption into the systemic circulation

Distribution

- A higher percentage of total body water than adults and a lower body fat composition
 - water-soluble drugs may be dosed at higher levels, lipid soluble drugs may have a decreased dose
- Low blood plasma protein concentrations
 - Risk for drug toxicity



Metabolism and Excretion

- Immaturity of liver and hepatic metabolism (prematures and infant)
 - Accumulation of medicine in the body
 - A prolonged half-life of medication
- Acceleration of hepatic metabolism (preschool-aged)
 - medications may need to be dosed more frequently than in adults
- Renal excretion is reduced in neonates and infants





Medicines that should be avoided in children

- Tetracyclines are not recommended for treatment in children younger than 8 years of age
 - Accumulate on growing bones and teeth → permanent damage to the bone and enamel
- Acetylsalicylic acid
 - Reye's syndrome
- Glucocorticoids
 - harmful to skeletal development and growth



Principles of pediatric medication

- Dosing in children is most often based upon the body weight (mg/kg), age or body surface area
- Pediatric dose should never exceed a normal adult dose
- Children should not be given medicines intended for adults without a doctor's prescription
- Make sure whether a single dose or a daily dose is prescribed
- Choose the appropriate dosage form
- Make sure that dosage range are suitable for use in children
- the child is involved in carrying out the medication
- Good guidance for parents!

Pediatric Regulation (EU 1901/2006)



- Came into force in Europe at the beginning of 2007
- Aims to improve European children's health by increasing
 - High quality pediatric research on efficacy and safety of medications
 - New medications go through Pediatric development programme
 - New medications and formulations are suitable for children (liquid form, mini tablets)
 - Marketing authorization of pediatric medicinal products
- Makes information on pediatric medicinal products available
- Regulation obliges pharmaceutical industry to investigate all new medicinal products designed for adults also on children and adolescents if they are regarded useful for the pediatric population
- Pediatric committee (under EMEA) assesses, advises and informs about implementing pediatric regulation
- In national level, local networks implement the regulation e.g. FINPEDMED in Finland

Results of pediatric regulation

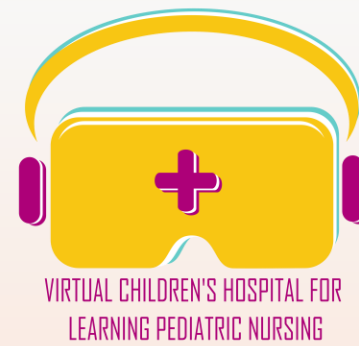
- More trials in children
- More medications
- More information
- More collaboration

Plans for the future:

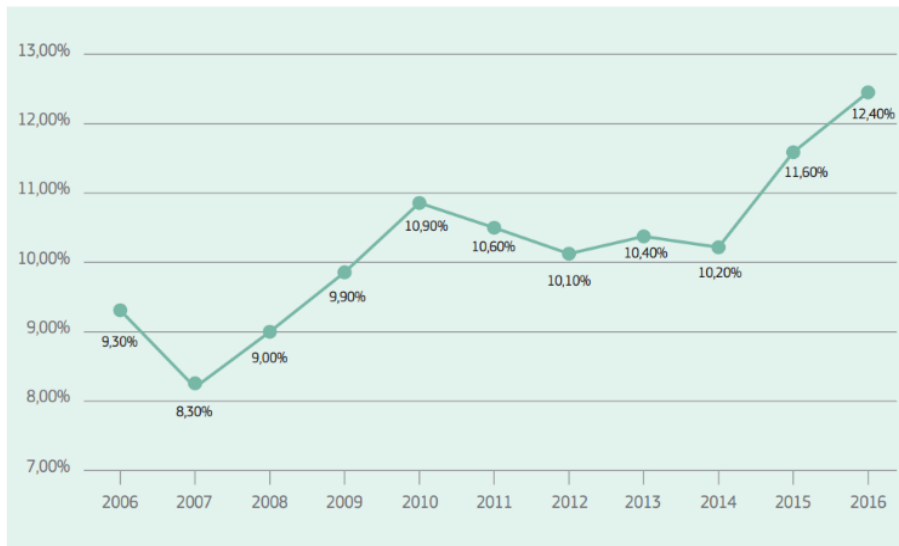
More open, more transparent



Results of pediatric regulation (years 2007-2016)

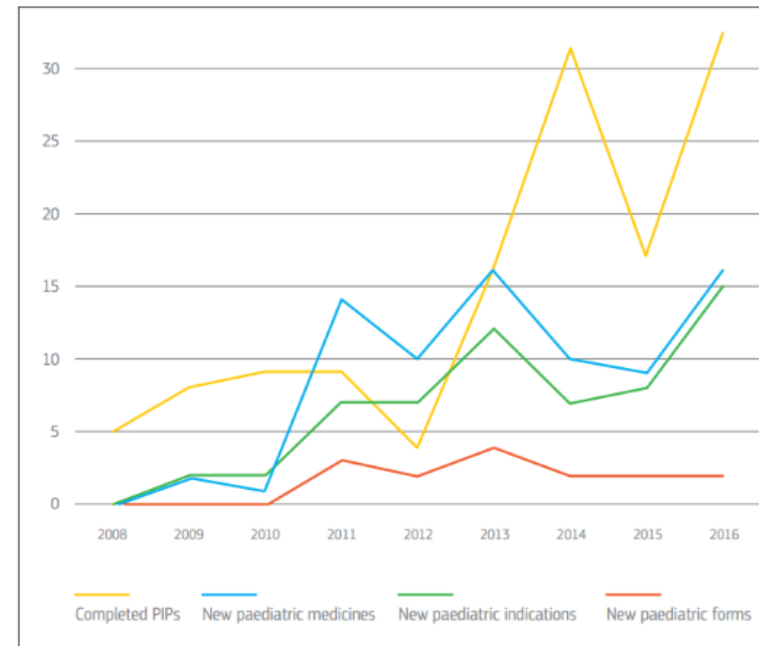


More paediatric trials



Source: EudraCT database

More authorised medicines



Source: EMA databases (only centrally authorised medicinal products).





References

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