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Access to Adequate Medicines for Children:

Persisting neglects and gaps

Jacquie Oliwa
Senior Researcher, Child and Adolescent Health

Background

- Paediatric formulations remain systematically unavailable, unaffordable, or inappropriate in many settings
- Children need:
  - age-appropriate dosage forms
  - flexible strengths
  - excipients safe for immature physiology
- >50% essential medicines lack suitable paediatric formulations
- Leads to a persistent pattern:
  - tablets dominate markets
  - liquids fill the gap (despite instability and dosing risks)
  - manipulation (crushing, splitting, diluting)
  - frequent off-label use

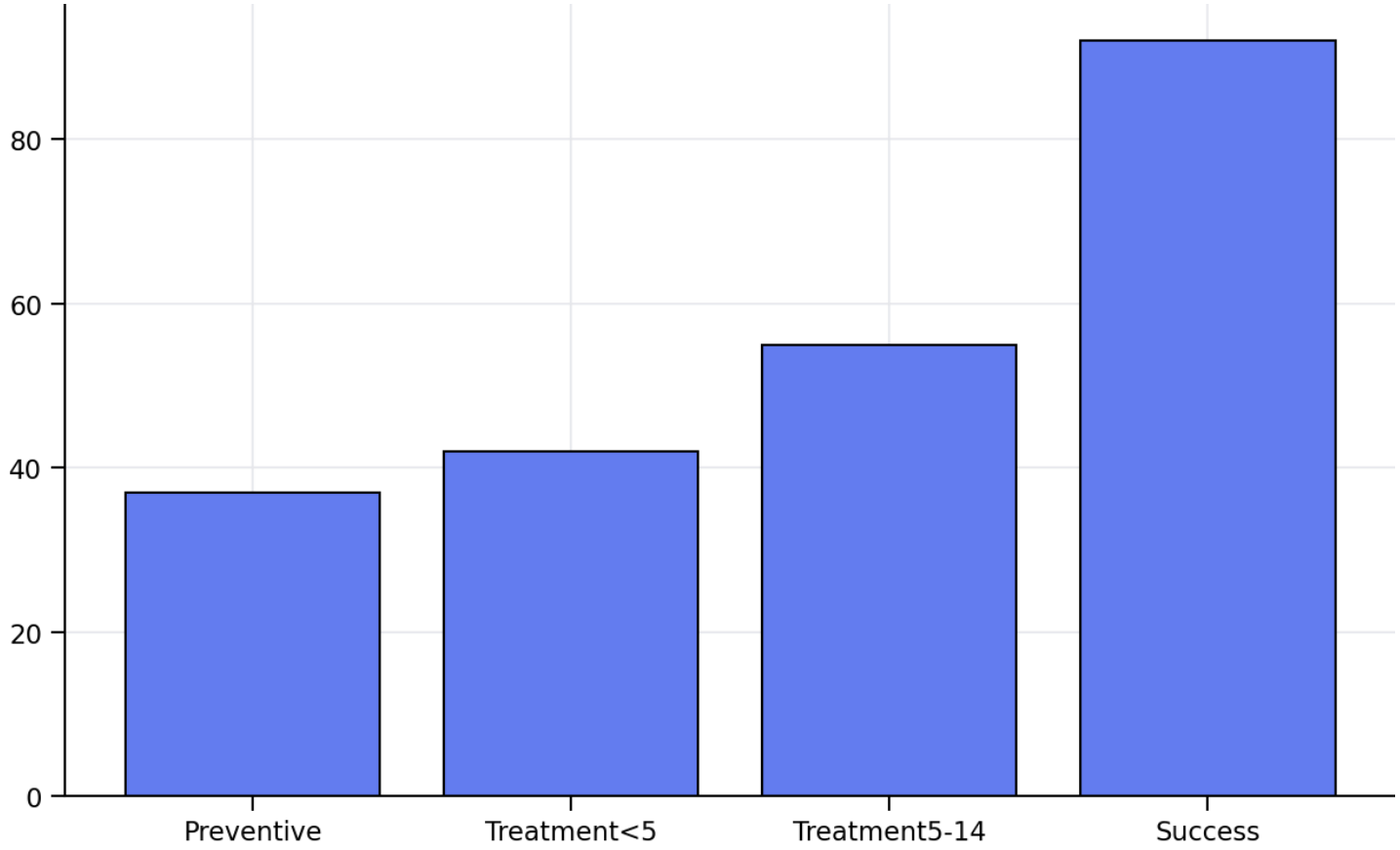
Children are a quarter of the world's population — yet they remain peripheral in how we define, study, and advocate for access to essential medicines.

Case of Paediatric TB

- Approx 1.2 million children get TB disease each year
- Almost 250,00 deaths/year
- >95% deaths occur in children never initiated on tuberculosis treatment.

Access is a problem!

- Yet children have high treatment success rates (92% for DS & 80% for DR)
- Access to TPT also a challenge



WHO Global tuberculosis report 2025

TB: Access to child friendly formulations

Weight band	Numbers of tablets	
	Intensive phase: RHZ 75/50/150*	Continuation phase: RH 75/50
4-7 kg	1	1
8-11 kg	2	2
12-15 kg	3	3
16-24 kg	4	4
25+ kg	*Adult dosages recommended*	

*Ethambutol should be added in the intensive phase for children with extensive disease or living in settings where the prevalence of HIV or of isoniazid resistance is high

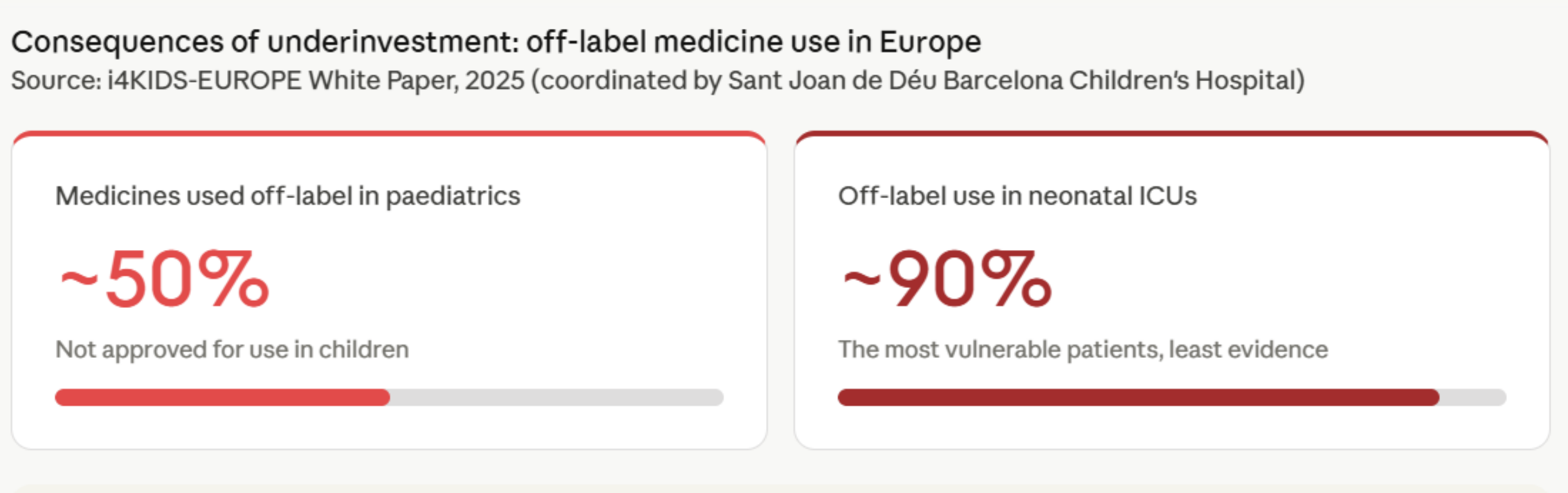
Paradox: FDC readily available in LMIC countries, but paediatric TB patients in HIC including Belgium still contend with high pill burden

Case of Amoxicillin

- Childhood pneumonia: leading cause of death
- WHO recommends amoxicillin dispersable tabets (DTs)
- Globally, only 22% of child oral antibiotic sales were DTs
- Syrups, the most used, create serious access problems:
  - bulky and fragile supply chains
  - cold-chain dependence
  - dosing inaccuracies and caregiver confusion
- UNICEF: when DTs are available, lack of appropriate packaging, labelling, and instruction gaps leads to poor adherence and treatment failure

Li G, Jackson C, Bielicki J, Ellis S, Hsia Y, Sharland M. Global sales of oral antibiotics formulated for children. Bull World Health Organ. 2020 Jul 1;98(7):458-466.

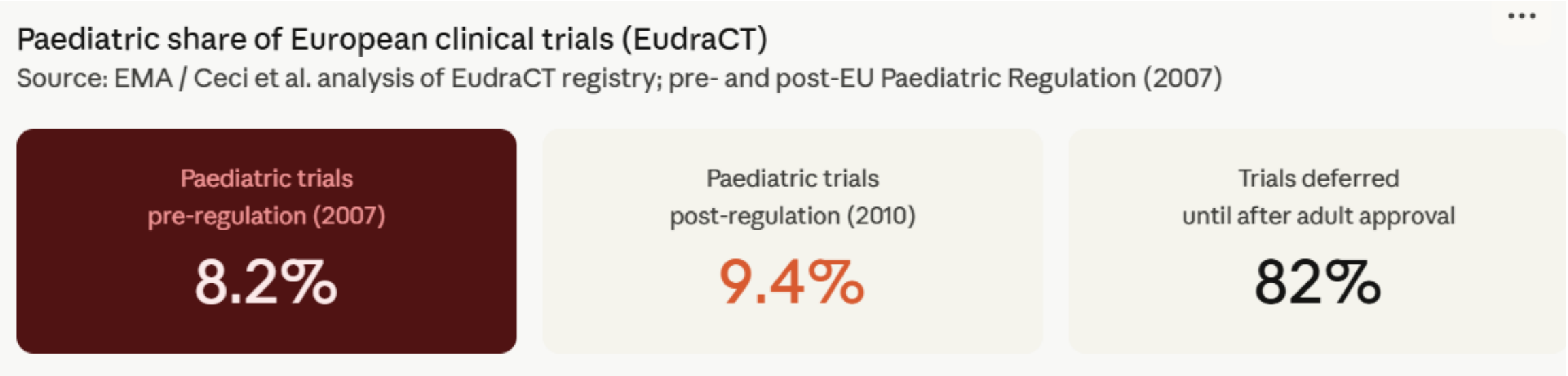
Case of off label use in paediatrics



These children technically have "access" to medicines — but not to formulations developed, tested, or labelled for them.

Research and development Gap

- Of all trials registered on the International Clinical Trials Registry Platform between 2000 and 2023, only 10% included children.
- Among uniquely paediatric trials, only 9% were in LMICs, 1% in LICs, and very few focused on the highest mortality period (birth/infancy)



Berkley J, Walson J, Gray G et al. ***Strengthening the paediatric clinical trial ecosystem to better inform policy and programmes****. The Lancet Global Health, 13, e732-e739, April 2025*

Regulatory and market gaps

- Small, fragmented markets: paediatrics doses divided by age and weight
- Delayed/no paediatric development: companies often defer paediatric studies
- Essential medicine ≠ commercially essential medicine: many off-patent, lifesaving medicines are cheap but unattractive to manufacturers.
- Results in structural neglect, esp. for:
  - neglected tropical diseases
  - antimicrobial formulations
  - chronic childhood conditions in low-resource setting

Heredia C, Ul Haq MZ, Cappello B, Malik F, Penazzato M, Moja L and Persaud N (2025) Pediatric formulations in national essential medicines lists: a cross-sectional study. Front. Pediatr. 13:1566841. doi: 10.3389/fped.2025.1566841

Hidden harms of poor access to paediatric formulations

- The consequences are largely invisible, but real:
  - increased medication errors
  - treatment failure due to under- or overdosing
  - poor adherence (bad taste, large volumes, frequent dosing)
  - ethical concerns
    - Children exposed to untested formulations
    - Widespread off-label use
- Silent contributor to avoidable morbidity and mortality

If essential medicines are meant to serve those most in need, then persistent gaps in access for children signal unfinished work!

Recommendations

1. Redefine EM access to include paediatric formulations
2. Treat paediatric formulation gaps as a core structural access failure
3. Reframe gaps to health and equity outcomes as part of UHC agenda
4. Develop a focused research agenda
5. Incentivise research, development and sustained supply

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Thank you!

Questions welcome

Jacquie Oliwa
joliwa@itg.be

ITGITMantwerp
@itmantwerp
@institute-of-tropical-medicine
@ITMantwerp @TropischITG