

Lack of tuberculosis trials in children unacceptable

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Ensuring the involvement of children in the evaluation of tuberculosis treatment is critical as we move forward in developing effective responses to active and drug-susceptible tuberculosis (TB), argues a new essay in this week's PLoS Medicine.

William Burman (from the Denver Public Health and the University of Colorado Health Sciences Center, Denver, USA) and colleagues say that children are an often ignored but important part of tuberculosis control efforts. In high-burden settings, children make up as much as 20% of new cases of active tuberculosis. Young children are also at high risk of having severe, rapidly-progressive forms of tuberculosis.

But nearly 40 years after the development of short-course treatments in adults, there are still major uncertainties about dosing for children of common TB drugs. "Only in recent years has there been a substantial effort to manufacture child-friendly formulations of first-line tuberculosis drugs (such as crushable mini-pills, granules, oral suspensions)," say the authors. "And in the past 15 years, children have been included in only one study of new agents for tuberculosis: a large Phase 3 trial evaluating once-weekly rifapentine + isoniazid for treatment of latent tuberculosis."

Including children in drug development is especially critical, say the authors, as the two main threats to tuberculosis control—HIV-related immunodeficiency and drug-resistant tuberculosis—challenge our ability to develop effective drug regimens.

Burman and colleagues outline several traditional barriers to the involvement of children in tuberculosis drug development such as difficulty confirming TB diagnosis, concern about side effects, and regulatory requirements. But they also describe how these barriers can be overcome, arguing that researchers, regulatory agencies, advocates, and government agencies and private

foundations that fund drug development must insist that the development pathways for all new treatments include specific plans for when and how children will be involved.

"Children have the same right to benefit from research as do adults," say the authors. "While this lack of involvement may be understandable in the short-term, it is not acceptable in the long-term."

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