Protecting Children Through Research

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ABSTRACT: Given the relative lack of pediatric clinical trials and the common pediatric use of untested or underinvestigated interventions in care, stakeholders increasingly recognize a need to bolster the trial-informed evidence base both in the United States and abroad. This need is particularly acute in the setting of drug trials. However, despite recent improvements in pediatric participation, children continue to be underrepresented. As explored in the article by Pathma Joseph and colleagues1 in this month's issue of Pediatrics, the problem has multiple causes and trials often fail to include any children or those who might benefit most from treatment. Building on the data presented by Joseph et al,1 we suggest that, although care must be taken to protect children, the best way to bolster outcomes and protect children is through research, not from research.

Frequently, drugs that are available for adults are not formulated and authorized for children. Medications available for treatment of the >3 million HIV-infected children worldwide are a telling example. Of the 6 regimens recommended for first-line treatment in adults with HIV in the United States, 4 are not currently licensed for use in children <12 years old or weighing <35 kg. The other 2 are not recommended for children <2 years of age.

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