

A PEDIATRIC DRUG TRIAL IN MY PRACTICE? EXPERIENCE, INTEREST AND DECIDING FACTORS AMONG RESEARCH-ORIENTED PRIMARY CARE

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Background: In 2007, the US Congress reauthorized the Best Pharmaceuticals for Children and Pediatric Research Equity Acts, continuing pharmaceutical industry incentives to conduct pediatric clinical trials to address the lack of drug safety and efficacy data for pediatric populations. The availability of pediatric primary care sites to participate in trials is, however, open to question.

Objective: To examine, among a group of primary care practitioners (PCPs) who have experience or have expressed interest in research: 1) experience with pediatric drug trials; 2) factors considered prior to participation; 3) types of trials they may be interested in; 4) their overall level of interest in doing pharmaceutical trials in their office.

Methods: The assessment was conducted via a brief online survey of the 981 subscribers to the email list of Pediatric Research in Office Settings, the national practice-based research network of the AAP. Members received an email invitation to complete the survey through a hyperlink to the survey website. One reminder email was sent. Existing network demographic data were used to describe the sample.

Results: Of the listserv members, 450(46%) responded to the survey. 30% of respondents had participated in a drug trial in the past and 10% said they were currently involved in a trial. 56% of respondents were *somewhat* or *very* interested in conducting trials in their office. PCPs with potential interest in trials were based in larger practices (74%, $p=.11$). They were significantly less likely than their counterparts to spend $\geq 90\%$ of their time practicing general pediatrics ($p=.02$). Among those with any level of interest in doing trials, 61% expressed interest in a CME course on conducting office-based drug trials. Notably, over 70% of respondents expressed interest in post-licensure studies of long-term effectiveness or side-effects and/or trials of drugs used off-label in children. The two most important factors for consideration prior to participating in a trial were minimal risk level to the patient and easily incorporated study designs.

Conclusions: PCPs involved in research display considerable interest in expanding participation to include pediatric drug trials. Interest is especially strong in post-licensure surveillance studies and examinations of off-label drug use in children. To realize this potential, however, greater opportunities for research training appear warranted.