Clinical Pharmacology in Children

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Do we need clinical pharmacology in children? Are children really different from adults in pharmacokinetic as well as pharmacodynamic responses? Should we conduct clinical trials in children?

These are the questions frequently asked when we talk about durg uses in children. Especially in dealing with the ethical problems in clinical trials involving special age groups, there have been myriad different viewpoints about the pros and cons.

The answer really lies in acknowledging that children, especially younger ones such as newborns, including premature babies, and infants, are not just a diminution of adults, but a dynamically evolving being with so much variation in structure and function that lest we study and treat them separately, we are placing ourselves in a difficult position where our clinical practice cannot be justified.

No doubt clinical pharmacology is necessary in children, because children need medicines. If we were to use medicines in children, we have to know the exact dose to be administered, what the fate of that durg would be in the body, what the effect of the drug on the body will be, and what kinds of adverse events may occur and be expected, as in adults. Although it is generally recognized that there exist pharmacokinetic and pharmacodynamic differences, only limited works on these aspects in children have been advocated because of various reasons such as ethical controversies and the question whether investment into these would be profitable.

Would it be ethically acceptable to use in children without proper controlled clinical trials drugs well-studied and proven safe in adults, considering the fact that clinical pharmacology in children is different, at least in part? Or should we perform studies on children who will not benefit directly from the results of the study? Would you expose your own children to investigational new drugs? How do weigh risk and benefit?

The questions are difficult to answer. Nevertheless, the pediatricians and clinical pharmacologists in the world have been under increasing pressure that calls for the proper clinical trials in children. FDA and American Academy of Pediatricians in USA, as well as pediatric societies in Britain and Europe, encouraged these studies to be performed and set the guidelines as early as in 1977. After almost 20 years of neglect, the pediatric clinical pharmacology has been getting attention just recently. And FDA is trying to resolve problems hindering the efficient execution of clinical traials in

children.

Therefore, it is evident that, as we should realize interindividual variations even in adults and try to optimize drug therapies for individual patients, we also should repect the different needs to be satisfied in treating children.