

OFF-LABEL USE OF DRUGS IN CHILDREN

Komarova A. P.

National University of Pharmacy, Kharkiv, Ukraine

komarova141@mail.ru

Introduction. For the pediatric population, gold standard clinical trials are often not available, so practitioners must rely on either less definitive information, such as expert opinion for the age group that they are treating, or use evidence from a different population to guide practice. Studies throughout Europe have shown that at least one-third of children in hospital and up to 90% of neonates in a neonatal intensive care unit receive off-label drugs. The medicines that are most frequently used off-label include analgesics, antibiotics and bronchodilators. The off-label use style – it's the appointment of drugs, without the express guidance in the instruction for applying. A common approach has been to use data from adults and adjust the dose according to a child's weight. But this trial-and-error approach has also resulted in tragedy, indicating that adult experiences with a drug aren't always a reliable predictor of how children will react.

Aim. To emphasize the importance of clinical researches off-label use of drugs in children.

Materials and methods. The FDA mandates that almost all new drugs and certain approved drugs must be studied if there is potential for use of that drug in children and that the application for new drug approval include the results of adequate pediatric studies. Linkages between the FDA, NICHD, AAP, and other organizations have been important for building a foundation for pediatric research, and children are getting more and better drugs by keeping pediatric drug research a high priority.

Results and discussion. The passage of the Best Pharmaceuticals for Children Act 2 (BPCA) and the Pediatric Research Equity Act 3 (PREA) has resulted in more than 500 pediatric labeling changes. Legislation of Ukraine does not contain any legal norms for off-label use of drugs. Art. 4, n. 3 “On Protection of Consumers” Rights Law of Ukraine said that it is necessary to use the product for its end use, and to adhere to the conditions (requirements, norms, rules), set by the manufacturer in the maintenance documentation. The problem that may be particularly acute in the near future, with the transition the health care system of Ukraine to medical insurance, introduction of modern quality control mechanisms for health care, including prescribing.

Conclusions. Off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics.