Study examines drug labeling and exposure in infants

9 December 2013

Federal legislation encouraging the study of drugs in pediatric patients has resulted in very few labeling changes that include new infant information, according to a study by Matthew M. Laughon, M.D., M.P.H., of the University of North Carolina at Chapel Hill, and colleagues.

Neonates (infants up to 28 days of age) are at high risk of drug-related adverse events and their unique physiology makes it hard to extrapolate data on drugs from older patients. Drug labeling often has insufficient information on the safety, efficacy or dosing that is appropriate for children, in part because there are few drug trials in neonates, according to the study background.

Researchers reviewed drug studies that included neonates, as a result of legislation, and assessed the types of drug labeling changes, if any, that were made. They reviewed Food and Drug Administration (FDA) databases and identified 28 drugs studies in neonates and 24 related labeling changes.

Study findings indicate 11 (46 percent) of the 24 neonatal labeling changes made clear the drug was approved for use in neonates on the basis of safety and effectiveness. Researchers then found that most of the studied drugs were not used in neonatal intensive care units (NICUs), with 13 (46 percent) of the 28 drugs studied in neonates not used and 8 (29 percent) of the drugs used in fewer than 60 neonates.

"Because of these challenges of performing clinical trials in infants, few labeling changes have included infant-specific information. Novel trial designs need to be developed and appropriate study end points must be identified and validated," the study concludes. "Education of parents and caregivers regarding the need for studies of drugs being given to neonates will also increase trial success. The scientific and clinical research community will need to work together with the FDA to conduct essential neonatal studies."

More information: *JAMA Pediatr.* Published online December 9, 2013. DOI: 10.1001/jamapediatrics.2013.4208