Adverse drug reactions may be under-reported in young children

September 7 2016

A new study reveals that adverse drug reactions in newborns and infants may be under-reported.

For the study, investigators analyzed 2001-2010 information from the UK Medicines and Healthcare products Regulatory Agency, which runs a national spontaneous reporting system to collect suspected adverse drug reaction data.

The researchers found that spontaneous reports alone are not currently generating required data, and important safety messages from the regulator do not match reporting patterns. Additional reporting strategies will be required to improve the quantity and quality of information on suspected adverse drug reactions in young children.

"The UK set up the first system in the world to report adverse drug reactions, the Yellow Card Scheme, over 50 years ago. It has helped improve the safety of drugs immensely by identifying adverse drug reactions, and continues to be valuable today," said Dr. Daniel Hawcutt, lead author *British Journal of Clinical Pharmacology* study. "This research shows that for newborn babies and infants, the spontaneous reporting of adverse drug reactions may not be enough, and additional systems to seek out and report adverse drug reactions are required."

More information: Daniel B. Hawcutt et al. Spontaneous Adverse Drug Reaction Reports for Neonates and Infants in the UK 2001-2010: Content and Utility analysis, *British Journal of Clinical Pharmacology*

(2016). DOI: 10.1111/bcp.13067