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Occurrence of adverse drug reactions in the paediatric population

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The safety of prescribed medicines is an important public health issue because serious adverse drug reactions (ADRs) may occur. Medicines are prescribed to children, although many drugs have been marketed with no or limited experience regarding the efficacy and safety in this population. Very few clinical trials involving children have focused on the efficacy of medicines and rarely have they covered safety. The aim of this presentation is to present findings with respect to occurrence, seriousness and type of reported ADR, therapeutic group, age and gender of the child and category of reporter.

The empirical analyses were based on registration files, published articles and ADR reports submitted to the national Danish ADR database. We analyzed 4500 ADRs submitted for children from ages 0 to 17 years to the Danish national ADR database from 1998 to 2007 and approximately 40% of these were serious. One-half of ADRs were reported in children from 0 up to 2 years of age. Approximately 17% of reported ADRs were associated with off-label use, 60% of them serious. The majority of ADRs were reported for immunization and antibiotics and psychotropic medicine. Serious ADRs due to off-label prescribing are more likely to be reported for hormonal contraceptives, anti-acne preparations and allergens. The majority of ADRs were reported by physicians. In conclusion there is a need for more research into the prescribing of medicines in the teenage population, as well as tighter reporting and monitoring of ADRs for medicines prescribed off-label.

Biography

Lise Aagaard graduated as a pharmacist (Msc pharm) in 2001. In 2008 she earned her PhD degree for analyses of how knowledge about adverse drug reactions can be improved. She has since 2008 joined the Department of Pharmacology and Pharmacotherapy, Faculty of Pharmaceutical Sciences, University of Copenhagen as an assistant professor and since 2010 as an associate professor. Her research is focused on medicines safety and policy, medicines use and pharmacoepidemiology. A special focus area is medicines safety in children; and several studies have been published on this topic.