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The extent of off-label and unlicensed drug use in neonatal intensive care units in Iran

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The present study was designed to evaluate the use of unlicensed and off-labeled drugs in neonatal intensive care units (NICU) of two academic hospitals in Iran. To our knowledge it is the first study done in this area in Iran. In this cross sectional study, all neonates that had at least 24 hour NICU admission, during the first 3 months of 2016, in two different hospitals were included in this study after their parental consent. The drugs were categorized as licensed, unlicensed and off-labeled according to Pediatric and neonatal dosage handbook (Lexicomp* 22nd Edition). 193 patients (52.85% M, 47.15% F), 64.2% of them delivered via C-section, were included in this study. Mean gestational weight was 409±3317 g for term babies and 1732±621 g for preterm neonates. A total of 1049 drug orders were made for these patients (including 59 agents and 72 drug formulations). The mean number of drug orders and pharmaceutical agents for each patient were 5.44±4.08 and 4.46±2.98 respectively. Preterm neonates had a higher number of drug orders and medications (p values 0.003 and <0.001). 38.04% of the drug orders were off-labeled (received by 85% of the neonates) and 1.91% unsilenced (used in 8% of the patients). 45% of the off-label use was regarding the dose and 36.86%, dose interval. 60.05% of the used drugs were licensed. It seems that due to the high rate of off-label and unlicensed drug use in NICUs, further studies regarding their safety and efficacy should be performed.

Biography

Leila Kouti became a board certified clinical pharmacist at the age of 29 years (2009) and completed her PhD three years later, from Tehran University of Medical Sciences. She is an assistant professor in clinical pharmacy department at Ahvaz Jundishapur University of Medical Sciences. She has published more than 20 papers in different journals.

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