

RESEARCH ARTICLE

Off-label drug use among hospitalised children: identifying areas with the highest need for research

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Objective of the study To analyse the off-label use of drugs on a paediatric ward in Germany, and to identify domains of pharmacotherapy with the highest need for research concerning off-label use in children. **Setting** A prospective observational study was conducted on a paediatric ward in Duesseldorf in Germany between January and June 2006. **Method** Data about patients, diagnoses and prescribed drugs were collected from the prescription records and the discharge letters. Diagnoses were classified in groups by means of the International Classification of Diseases. Drugs were grouped according to the Anatomical Therapeutic Chemical Classification system. We compared the off-label prescriptions with those on the list of paediatric needs and priority list established by the European Medicines Agency (EMA). **Main outcome measure** Offlabel use was defined due to age, indication, route of application and dose. **Results** The study included 417 patients. We analysed 1,812 prescriptions representing 211 different drugs. In total, 253 patients (61%) received at least one off-label prescription. Of all analysed prescriptions, 553 (31%) were off-label. The percentage of offlabel prescriptions among the five most frequently prescribed drug groups were as follows: 60% cardiovascular drugs (CV: 129/216), 42% anti-infectives (AI: 190/449), 30% drugs for respiratory system (RS: 100/335), 25% drugs for alimentary tract and metabolism (AM: 67/269) and 3% analgesics and antipyretics (AA: 8/264); with 17 drugs, the cardiovascular drugs also showed the highest number of different off-label prescribed drugs due to age: AI: 14; AM: 11; RS: 5; AA: 1. In addition, there was a nearly complete overlap between the identified off-label prescriptions in cardiovascular drugs and those listed by the EMA to be prioritized for urgent research in Europe.

Conclusion Cardiovascular drugs are a domain of pharmacotherapy, with a large need for research in paediatrics. The results of our study can guide the researcher to future trials on off-label prescriptions such as cardiovascular drugs, especially due to the fact that the identified off-label prescribed drugs in this group are also mentioned by the EMA to be prioritized for paediatric research.

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