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Off-label paediatric drug use in an Indonesian community setting

R. Abdulah* PhD, M. A. Khairinisa* BPharm, A. A. Pratiwi* BPharm, M. I. Barliana† PhD, I. S. Pradipta* MSc, E. Halimah* PhD, A. Diantini* PhD and K. Lestari* PhD

**Department of Pharmacology and Clinical Pharmacy, Faculty of Pharmacy, Universitas Padjadjaran, Jatinangor, and †Department of Biological Pharmacy, Faculty of Pharmacy, Universitas Padjadjaran, Jatinangor, Indonesia*

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SUMMARY

What is known and objective: **Off-label medication is often used in the treatment of paediatric patients. However, it should be restricted due to the lack of evidence related to its efficacy and safety. Little is known about the frequency of off-label drug use or the degree of scientific evidence supporting this practice in Indonesia. The aim of this study was to investigate the off-label prescribing practice for paediatric patients in Bandung city, Indonesia.**

Methods: **We conducted a retrospective and population-based study including 4936 prescriptions written by paediatricians for 0- to 5-year-old patients from 14 selected community pharmacies in 2012 and analysed the off-label uses.**

Results and discussion: **Of the total prescriptions, 18.6% contained at least one off-label drug. Furthermore, 7% of the 16 516 prescribed drugs were categorized as off-label. Of all of the prescribed drugs, doxycycline and domperidone were the most prescribed drugs with off-label indications.**

What is new and conclusion: **This is the first study that shows a significant number of off-label drugs prescribed for children in Indonesia; therefore, efforts should be made to scrutinize under-evaluated off-label prescribing practices that may compromise patient safety.**

WHAT IS KNOWN AND OBJECTIVE

Off-label drug use (OLDU) occurs when a drug is used in a manner deviating from its approved use or its marketing authorization. Pharmacotherapy is usually based on drugs that are approved for specific indications, dosages, routes of administration or populations. However, this does not preclude the use of the medicine outside of those terms. Although there is generally a lack of sufficient evidence on risk/benefit assessment, OLDU is a common practice.[1–3] In fact, in some cases, it is clinically more important than the use of medicine for approved purposes[4] as it may represent the most logical evidence-based therapy.[5]

In paediatric practice, OLDU prescribing is common because clinical trials are usually not conducted in children during the development process of the medication. Therefore, the provided information may not be as detailed as when prescribing a medicine that is licensed for an approved indication. Off-label drug use for younger children can be prescribed at a different dose, for a different indication or by a different route of administration than what the drug is licensed for.[6] The potential health risks are unknown, which may lead to an important public health issue. Dost, a paediatrician, has stated that children differ pharmacokinetically from adults and medication for adults cannot simply be administered in smaller doses.[7]

There are several problems associated with the lack of reliable data for the paediatric population, including limited availability of safety data due to the lack of clinical trials and insufficient pharmacokinetic data or dose-finding studies. Maturation, growth and development make the paediatric population susceptible to drug-induced growth and developmental disorders and delayed adverse drug reactions (ADRs).[6] Thus, OLDU in children is a potential risk factor for ADRs.[8,9] Paediatricians should be aware that the use of OLDU may increase the risk of adverse reactions.[10]

Even in developed countries, the percentage of authorized medicines for children is only 33.3%.[11] This has caused the absence of appropriate drug formulations for paediatric patients, that is oral solutions or small enough tablets. Furthermore, dosing recommendations for children have often been decided by scaling from adult dosage, which does not provide sufficiently adequate estimates.[12] Therefore, most of the therapies prescribed to children are off-label.[13] It is important to explore the best strategy to find as many relevant studies as possible. Therefore, this study aimed to collect comprehensive and detailed information about prescribed drugs to estimate the use of off-label medications in paediatric patients.

METHODS

Data collection and study populations

We conducted a retrospective and population-based study that included 14 randomly selected community pharmacies in Bandung city, Indonesia, in conjunction with our previous research.[14] Briefly, prescription data from paediatricians for all patients aged 0–5 years during 2012 (from 1st January to 31st December 2012) were processed. Detailed information from each prescription was recorded, including the patient's age and name and the route, dose and frequency of all prescribed medicines.

All participating community pharmacies received written and verbal information about the design and purpose of the study. The study was conducted according to the guidelines of the Declaration of Helsinki. Written informed consent was not required because this was a retrospective observational study. No medical interventions were performed during the study. All ethical considerations were followed. Patient files were processed anonymously. No personal data were collected. The study protocol was approved by the Universitas Padjadjaran Ethics Committee.

Correspondence: Rizky Abdulah, PhD, Department of Pharmacology and Clinical Pharmacy, Faculty of Pharmacy, Universitas Padjadjaran, Jl. Raya Bandung Sumedang KM. 21, Jatinangor 45363, Indonesia. Tel.: +62-22-7796200; fax: +62-22-7796200; e-mail: abdulahrizky@gmail.com