



ORIGINAL ARTICLE

Frequency of prescriptions of off-label drugs and drugs not approved for pediatric use in primary health care in a southern municipality of Brazil



Marcele Giacomini Gonçalves*, Isabela Heineck

Faculdade de Farmácia, Universidade Federal do Rio Grande do Sul (UFRGS), Porto Alegre, RS, Brazil

Received 3 March 2015; accepted 16 June 2015

Available online 30 December 2015

KEYWORDS

Pediatrics;
Medication use;
Primary health care

Abstract

Objective: To determine the frequency of prescriptions of off-label drugs and drugs not approved for pediatric use in primary health care in medium-sized municipality of Rio Grande do Sul, Brazil.

Methods: Cross-sectional study with retrospective data collection, which analyzed prescriptions issued to 326 patients from August to December/2012 in two basic health units in the city of Viamão, state of Rio Grande do Sul. It included all prescriptions of patients whose medical records or service records were available and complete in relation to the date of presence, weight and date of birth. Off-label prescriptions were those which, in relation to the drug leaflet, showed dose different the recommended range, frequency of prescription and/or different form of administration and younger age than the indicated range. Descriptive statistics with absolute frequencies, means and standard deviations were used.

Results: During the study period, a total of 731 drug prescriptions were issued and the frequency of off-label medications prescribed was 31.7%, especially antihistamines and antiasthmatics (32.3% and 31.5%, respectively). The main type of off-label prescription was dose (38.8%), followed by age range (31.5%) and frequency of administration (29.3%). Regarding the dose off-label prescription, overdose was more frequent (93.3%) than the underdose (6.7%). Prescriptions of unapproved drugs were not identified.

Conclusions: The study showed that off label prescription is common in both assessed units. The observed percentage of off label prescription was higher than that reported by European studies carried out in primary care. On the other hand, the prescription of drugs not approved for children was not observed.

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* Corresponding author.

E-mail: marcele_gg@yahoo.com.br (M.G. Gonçalves).

PALAVRAS-CHAVE

Pediatria;
Uso de
medicamentos;
Atenção primária
à saúde

Frequência de prescrições de medicamentos *off label* e não licenciados para pediatria na atenção primária à saúde em município do sul do Brasil

Resumo

Objetivo: Determinar a frequência de prescrições de medicamentos *off label* e não licenciados para pediatria na atenção primária à saúde em município de médio porte do Rio Grande do Sul, Brasil.

Métodos: Estudo transversal, com coleta retrospectiva, que analisou prescrições a 326 pacientes emitidas de agosto a dezembro de 2012 em dois postos de saúde do município de Viamão. Foram incluídas todas as receitas de pacientes cujos prontuários ou fichas de atendimento estivessem disponíveis e completos em relação à data de atendimento, peso e data de nascimento. Foram classificadas como prescrições *off label* aquelas que, em relação à bula do medicamento, apresentavam dose diferente da recomendada, frequência de prescrição e/ou forma de administração diferente e idade inferior àquela indicada. Foi usada estatística descritiva, com frequências absolutas, médias e desvio padrão.

Resultados: Durante o período estudado houve a prescrição de 731 medicamentos e houve frequência de 31,7% de medicamentos prescritos *off label*, especialmente anti-histamínicos e antiasmáticos (32,3% e 31,5%, respectivamente). O principal tipo de prescrição *off label* foi dose (38,8%), seguida de idade (31,5%) e de frequência de administração (29,3%). Com relação à prescrição *off label* de dose, foi mais frequente a sobredose (93,3%) do que a subdose (6,7%). Não foram encontradas prescrições de medicamentos não licenciados.

Conclusões: O estudo mostrou que a prescrição *off label* é comum nas duas unidades estudadas. O percentual de prescrição *off label* observado foi superior ao relatado por estudos europeus feitos na atenção primária. Por outro lado, não foi observada prescrição de medicamentos não licenciados para crianças.

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Introduction

Considering the lack of drugs for use in children, especially those under 2 years of age, the off-label prescription drugs have become a routine practice both in hospitals and ambulatory and brings doubts to prescribers and providers regarding the benefit to the pediatric patient.^{1,2}

The term "off-label" refers to drugs prescribed in different manner than that directed in the instructions or official compendia in relation to dose, indication, age group, dosing interval, or form of administration.³ Off-label prescription is not illegal; it is not necessarily incorrect and is present in several pediatric protocols. The quality of drug therapy is not necessarily related to the licensing status of the drug. However, there are several clinical, ethical, and safety factors that should be considered and there are no guidelines to assist off-label prescription. The decision on this type of prescription should be assessed according to clinical indication, treatment options, and risk-benefit analysis. Moreover, it must obtain the patient's or guardian consent, taking care to avoid exposing children to unnecessary risks.⁴

Regarding the concept of unlicensed medicine, some authors consider that it refers to drugs that are unregistered in the surveillance agency, or are extemporaneous preparations, or drugs containing non-pharmacological chemical ingredients used with therapeutic purpose.⁵⁻⁸ Ferreira et al. extend the concept of unlicensed to registered drugs that are contraindicated for children.⁹

There are studies that characterize the extent of off-label prescribing in pediatric hospitals in Brazil,⁹⁻¹¹ but little is known of outpatient prescription in primary care. This study aims to fill this gap, determine the frequency of prescription of off-label and unlicensed drugs for pediatrics, to support the development of actions to promote rational use of drugs.

Method

Cross-sectional study with retrospective data collection, approved by the Research Ethics Committee of the Universidade Federal do Rio Grande do Sul (No. 214 535) and authorized by the Municipal Secretary of Health of Viamão. Data collection was performed in two basic health units: Family Health Strategy (FHS) Itapuã and Reference Unit (RU) Lomba Sabão, Viamão. Viamão is a city of the metropolitan area located 20.6km from the capital Porto Alegre, with an area of 1494.26km² and 239,384 inhabitants, according to the Demographic Census of the Brazilian Institute of Geography and Statistics (IBGE) 2010.¹²

Sample size calculation was performed considering 3759 pediatric consultations in health facilities involved during a period of five months (August–December 2012). A 20% expected frequency of off-label prescription drugs was used.^{4-8,13-16} To a 95% confidence interval, a 20%+5% range was considered. Thus, it was estimated that at least 231 prescriptions should be evaluated.

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