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Original article

Perceptions and attitudes towards off-label dispensing for pediatric patients, a study of hospital based pharmacists in Jordan

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ABSTRACT

Background: With growing responsibility of the pharmacists in ensuring public health and safe medicine use, an understanding of the issues surrounding off-label prescribing is crucial to allow pharmacists to make informed decisions about such practice. The aim of this study is to assess the perceptions and attitudes of hospital based pharmacists toward off-label medicine dispensing to children.
Methods: After obtaining the required approvals, a validated questionnaire about off-label dispensing to pediatric patients was administered to 250 randomly selected hospital pharmacists.
Results: One hundred and fifty (150) completed questionnaires were returned. Less than half of the respondents (44%, n = 66) admitted to being familiar with the concept of off-label dispensing, claiming to have obtained this knowledge basically through their dispensing experience rather than education. A minority of respondents (36%, n = 54) reported dispensing off-label medicines within their practice knowingly. The majority of respondents had concerns regarding the efficacy (82%, n = 123) and safety (98%, n = 147) of off-label medicines. The most common reasons given by respondents for a dispensed prescription being off label were younger age than recommended (88%, n = 132). Most of respondents (94%, n = 141) claimed to double check the calculations of doses of medicines before dispensing off-label medicines and 60% (n = 90) of them felt that parents and guardians should be told when an off-label medicine has been prescribed for their children.
Conclusion: The majority of respondents were not familiar with the concept of offlabel medicines. While reporting to have gained their knowledge from their professional experience, only a minority of respondents reported knowingly dispensing off-label medicines for pediatric patients. Respondents indicated that manufacturing more appropriate formulations for pediatric patients would reduce such practices in this population. Having concerns regarding the efficacy and safety of off-label medicines used for pediatric patients, respondents felt that the use of off-label medicines would increase the likelihood of adverse drug reactions (ADRs). Finally, respondents felt that such practice of prescribing and dispensing should receive parental consent.

1. Introduction

The off-label prescription of medicine for pediatric patients is a common practice worldwide (Pandolfini and Bonati, 2005). Off-label medicines are medication that have been prescribed outside of their product license in terms of their recomended age, recommended dosage, method of administering or advised use (Pandolfini and Bonati, 2005). A review from 1985 to 2004 by Conroy et al., (2000) revealed that up to 80% of prescriptions to children were prescribed in an off-label manner. Such a finding

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raises concerns about the safety and effectiveness of medication when they are prescribed to pediatric patients in this manner (Mukattash et al., 2011a, 2011b). It therefore emphasizes the importance of the role of healthcare providers in making sure that pediatric medicines are employed in the most appropriate manner (Turner et al., 1999).

The prescription of pediatric off-label medication has raised significant concerns with respect to reported increased rates and seriousness of adverse drug reactions (ADRs): There are also issues surrounding the possibility that the prescribed treatments will fail, as well as the problem of ensuring the safety and efficacy of any treatments administered over long term (Turner et al., 1999). Nonetheless, the prescription of off-label medication is commonplace since more beneficial treatments for children are often not available, while trials for many medicines intended for children have in fact not been carried out (Wong et al., 2003).

Prior studies have attempted to gain some understanding of the opinions and experience of healthcare professionals with regards to the phenomena of off-label prescriptions for children (Ekins-Daukes et al., 2005; McLay et al., 2006; Mukattash et al., 2011a, 2011b; Stewart et al., 2007). It has been found that healthcare professionals have a moderate level of awareness of this issue, which they obtained through their profession experience and development, as well as through their undergraduate and post-graduate education and training.

The research presented in this work was designed to build upon previous literature and to examine the knowledge and attitudes towards the prescription of off-label medication in Jordan. The importance of this arises from the fact that most previous work dealing with the prescription of off-label medicines has been undertaken in the USA, the United Kingdom and other European countries (McLay et al., 2006; Mukattash et al., 2011a; Mukattash et al., 2008; Stewart et al., 2007). In fact, this paper represents the first study of these issues, from a pharmaceutical perspective, with the entire Middle East.

The objective of this study is to examine the perceptions and attitudes of Jordanian hospital pharmacists towards the dispensing of off-label medicines to pediatric patients.

2. Methodology

2.1. Questionnaire development

Following a review of the literature, a questionnaire was developed which, while focusing mainly on the use of off-label pediatric medicines, also looked into the role of hospital based pharmacists in terms of giving information to parents about the use of off-label medicines in pediatric patients. The questionnaire was mainly based on those previously used to explore the views, attitudes, knowledge, and perceptions of different healthcare professionals towards the use of unlicensed and off-label medicines in pediatric patients (Ekins-Daukes et al., 2005; McLay et al. 2006; Stewart, et al. 2007; Mukattash et al. 2011a; Mukattash et al. 2011b). Most of the questions had pre-formulated answers, except for those where a reason for the participant's answer was required. The resulting questionnaire consisted of a total of 27 questions.

The questionnaire was divided into four sections addressing different topics of interest. The first section (questions 1–9) focused on the area of medicine use in pediatric patients and on the use of off-label medicines for pediatrics. The second part (questions 10–13) was concerned with the involvement of parents in deciding what medicine will be prescribed to their child. The third section (questions 14–16) dealt with issues surrounding the dosages recommended when dispensing off-label medicines to pediatric patients. The fourth and final section (questions 17–27) involved collecting the participants' details and relevant demographic information in order to assess any variability in the responses as a function of these factors. As part of the questionnaire, information about the off-label use of medicines in pediatric patients, including definitions and relevant examples, was provided to assist those participants who may not have been familiar with the employed terminology.

The questionnaire was first issued to a small sample of pharmacist (n = 20) working at the School of Pharmacy of the Jordan University of Science and Technology. These participants informed the authors that the questionnaire was clear and easily understood. Note, while these questionnaires were not included in the final analysis, they nonetheless showed similar results as those making up the rest of the study.

2.2. Data collection

The final questionnaire was distributed to a selection of pharmacists working in a list of randomly chosen hospitals. Hospitals were randomly selected from a list including all hospitals in Jordan. Before data collection, a letter was sent to pharmacy departments of all hospitals who were selected to take part in the study. The letters were sent to the head of each pharmacy department to ask them if they were willing to have their pharmacists take part in this study and if this was the case, they were also asked to indicate the number of questionnaires that would be required in each unit. Twelve hospitals agreed to take part in the study, seven public hospitals, four private hospitals, and one university hospital. In August and September 2014, questionnaires were provided to those departments who had agreed to take part in the study, asking that they complete it within four weeks. Those who had not completed the questionnaire within four weeks were allowed another two-week period before the questionnaire was collected again.

2.3. Ethical approval

The study received ethical approval from the Institutional review board at King Abdulla University Hospital in May 2014 (REF: 73-2014). The study was undertaken following the ethical methods and standards outlined in the guidelines provided by the World Medical Association Declaration of Helsinki (Association, 2013).

2.4. Data analysis

After collecting the completed questionnaires, the responses were transcribed and entered into SPSS for Windows, version 21, for statistical analyses. The main descriptive analysis was carried out using the derived mean and standard deviations (SD) for the continuous parameters, and percentages for the qualitative variables.

3. Results

3.1. Demographics

The questionnaires were distributed to a total of 250 randomly-selected pharmacies based in hospitals distributed throughout Jordan. A response rate of 60% (n = 150) was obtained after two visits. The majority of participants were female (62%, n = 93). Regarding their experience years, 70% (n = 105), had been working as hospital pharmacists for more than ten years and the majority of participants (80%, n = 120) reported more than 20 h per week of direct patient contact. The majority of participants (60%, n = 90) reported that pediatric prescriptions formed more than 20% of their

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