

Pediatric dosing errors due to variable drug formulations

Sir,

Dosing errors are not uncommon in day-to-day clinical practice in children. Pediatric patients are more vulnerable to adverse drug events because of small body size and need for weight based dosing.^[1-3] Among various reasons, one of the reasons for dosing errors in pediatric patients is, availability of different formulations with variable concentration of drugs.^[4] We present three cases where errors had occurred due to this in order to highlight such dosing errors and to raise awareness among clinicians.

A 6-year-old male child presented with complaints of giddiness and frequent falls since 2 days. The symptoms started after the patient had started using a different brand of prescribed antiepileptic drug (phenytoin). The patient was previously using the prescribed medicine with a concentration of 30 mg/5 ml; but this had been replaced with another brand with a concentration of 125 mg/5 ml. Thus, instead of receiving 7.5 ml twice a day (or a total dose of 90 mg at the rate of 5 mg/kg/day), the patient ended up receiving a total dose of 375 mg at the rate of 20.8 mg/k/d. The investigations revealed high levels of serum phenytoin. In another case, a 4-year-old female child (weight: 15 kgs) was referred for kidney biopsy and management after being diagnosed with steroid resistant nephrotic syndrome. She was advised treatment with prednisolone (10 mg thrice daily). She underwent extensive investigations to rule out secondary causes, but all were inconclusive. It was found that inadvertently prednisolone 5 mg thrice daily was being administered instead of 10 mg thrice daily, as prescribed. This aspect had been overlooked by all clinicians prior to referral to our hospital. Another 2-year-old male child presented with recurrent vomiting after intake of medication prescribed during a course of acute gastroenteritis. The medications were checked and it revealed the patient was receiving a zinc formulation with a concentration of 20 mg elemental zinc/ml as drops instead of 5 ml syrup with a concentration of 20 mg/5ml. Thus, the dose given was 5 times the prescribed dose.

Clinicians may have come across similar cases in their practice. Various studies are available citing multiple reasons and possible preventive aspects for the reduction of such errors.^[2,3] The chances of similar errors are greater with drugs available in different formulations and fixed dose combinations with different components and variable concentrations.^[4] Fortunately, none of our patients had serious

effects and recovered after remedial measures were initiated. Nevertheless, these cases reveal that there still remain serious lacunae in drug prescription and dispensing which might result in morbidity.^[1,3] A list of some medications variable concentrations in different formulations, that have potential to cause confusion have been enumerated in Table 1.

Higher concentration may be helpful to ease the administration of the medicine, but it raises the chances of adverse reactions if the proper dosage has not been explained. The ability of parents to understand medication dosing is definitely related to literacy rates. Hence, the dose, formulation and frequency of the prescribed medication must be clearly explained to the parents.^[5,6] Improving communication skills among health workers and a description of the medication in the local language would be helpful.^[1] Drug dispensing should be done by trained personnel only. Cross checking before the use of medications will help to reduce the possibility of such errors.^[7] Pictographic depiction of dosage also reduces the chances of errors.^[8] Another initiative could be dispensing of medication with different concentrations in different packaging/color graphics by pharmaceutical companies, so that formulations are easily differentiated by parents. Since parents are not comparable to skilled health care professionals, it is the responsibility of the clinicians to take suitable measures to avoid similar mishaps.

Table 1: List of medications with different concentrations in similar formulations

| Name of drug | Formulation 1 | Formulation 2 |
|--------------|-----------------|--------------------------|
| Domperidone | 1 mg/ml | 10 mg/ml |
| Iron | 10 mg/ml drops | 25 mg/ml drops |
| Paracetamol | 100 mg/ml drops | 120 mg/5 ml, 250 mg/5 ml |
| Phenytoin | 125 mg/5 ml | 30 mg/5 ml |
| Prednisolone | 5 mg/5 ml | 15 mg/5 ml |
| Vitamin D | 400 IU/ml drops | 3000 IU/ml drops |
| Zinc | 20 mg/ml drops | 20 mg/5 ml syrup |

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Received: 01-12-2013

Revised: 08-03-2014

Accepted: 03-05-2014

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10.4103/0976-500X.142444