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U S I N G P O I S O N S C E N T R E D ATA F O R PHARMACOVIGILENCE – SHOWING THE DANGERS OF RANITIDINE SYRUP FORMULATION

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Objectives: We noted a number of calls made to the UK National Poisons Information Service (NPIS) regarding excessive therapeutic doses of ranitidine being given to young children. We therefore investigated overdoses reported to the NPIS involving ranitidine, chlorphenamine, carbamazepine and sodium valproate syrups in order to determine whether the poisons centre calls had highlighted a common therapeutic error.
Methods: Using data extracted from UKPID, a centralised NPIS telephone enquiry database, we reviewed the number and nature of incidents involving ranitidine, chlorphenamine, carbamazepine and sodium valproate between 01/07/2007 and 31/03/2012.
Results: The NPIS received 374 calls regarding ranitidine overdose; 315 (84.2%) involved children aged under 5. Ranitidine syrup was the agent in 223 (70.8%) calls regarding patients aged under 5, and 218 (97.8%) of these cases were therapeutic errors. In the 174 cases where the circumstances of the therapeutic overdose were known, 61 (35.1%) were due to a 10x excess dose of syrup; the mean overdose was an 8.0x overdose. 16.3% (61/374) of all calls to the NPIS about ranitidine alone regarded a 10x therapeutic overdose. Chlorphenamine was the subject of 629 calls. Three hundred and sixteen (50.2%) involved patients aged under 5; syrup was taken by 207 (65.5%) of these patients. One hundred and thirty-seven (66.2%) chlorphenamine syrup ingestions were therapeutic errors; 66 (31.9%) were accidental. In the 68 cases where the circumstances were specified, 1 (0.73%) was a 10x therapeutic overdose, 10 (14.9%) were 4x overdoses, and 34 (50.0%) were due to a double dose. The mean overdose in these cases was a 2.6x overdose. Of 36 calls regarding excess therapeutic doses of carbamazepine or sodium valproate syrup given to patients aged under 5, none involved a 10x therapeutic dose.
Conclusions: Call details collected by poisons centres can be a valuable resource for pharmacovigilence. Using this information to study overdoses spread across time and place allows data regarding relatively common errors, possibly seen once by a primary care physician, to be noticed, analysed, and acted upon. In this investigation, over one-third of calls to the NPIS regarding children under 5 ingesting ranitidine were found to involve a 10x therapeutic overdose; only one such therapeutic error was seen in the same age group ingesting three other medicines. We believe this may be due to carers being more used to administering 'teaspoon'-sized doses of other paediatric preparations; a reformulation of ranitidine syrup for use in paediatric patients may prevent such large dosing errors.