Median toxicity/patient was 3 (1–13), appearing in an average time of 18 months (28 days–8 years) and 10 months (8 days–7 years) for TH (23/122) and NHT (99/122), respectively. Dose was reduced because of toxicity in 7/37 patients and was discontinued in 14/37.

Conclusion and relevance The analysis has allowed the implementation of a specific proactive follow-up for each drug, which means early recognition and management of the toxicities associated with TKIs to optimise treatment efficacy and safety, as well as patient quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-096 HAZARD VULNERABILITY ANALYSIS TO EVALUATE THE RISK OF DRUG SHORTAGES ACCORDING TO THERAPEUTIC CLASS

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Background and importance Drug shortages are a critical challenge for the public health system, as highlighted by EAHP's position paper. They have a negative impact on quality and efficiency of patient care.

Aim and objectives The aim of our study was the application of a revised hazard vulnerability analysis (HVA) to assess which therapeutic classes of drugs are at greatest risk of shortages.

Material and methods In September 2019, we analysed the drugs present in our hospital therapeutic formulary and checked which ones were included in the Italian Medicines Agency shortages list: 43 drugs were found.

For each drug, we assigned a score using a revised HVA which consists of three macro areas: probability that the shortages will occur, magnitude factors which increase the risk of shortage and mitigation factors which reduce it. For probability, a score from 0 to 2 was assigned based on previous shortages.

Magnitude factors were relevance of active substance, budget impact and percentage of patients treated. Mitigation factors were therapeutic alternative, stock availability and import of the drug. For each of these items a score from 0 to 3 was assigned. For magnitude factors, an increasing score was assigned as severity grew. In contrast, for mitigation factors, an increasing score was assigned in relation to mitigation reduction. The value of the risk was calculated by multiplying the percentage of probability (p) and the percentage of severity (S). According to the score obtained, three classes of risk of shortages were assigned: low (<30%), medium (30–60%) and high (>60%).

Results Of the 43 deficient drugs, 32/43 (74.4%) were at low risk of shortages while 11/43 (25.6%) were at medium risk. No drug was found to be at high risk of shortages (>60%): 2/11 were cardiovascular myocardiotropics (fructose sodium diphosphate); 3/11 were antiviral drugs (foscarnet, didanosine); 1/11 was an opioid analgesic (morphine); 2/11 were antimicrobial drugs (oxacillin sodium salt and piperacillin/tazobactam); 1/11 was a pneumococcal vaccine; 1/11 was a benzodiazepine anxiolytic (lorazepam); and 1/11 was an anthelmintic (albendazole).

Conclusion and relevance Analysis of shortages is essential to prevent the discontinuation of important therapies, such as those involving antiviral and antimicrobial use, and implement appropriate mitigation actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-097 POTENTIALLY HARMFUL EXCIPIENTS IN NEONATAL AND PAEDIATRIC PATIENTS

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Background and importance Excipients are essential to improve the quality, stability, bioavailability and patient acceptability of medicines. Most pharmaceutical excipients are recognised as safe. However, there are potentially harmful excipients for vulnerable group of patients, such as children younger than 4 years of age.

Aim and objectives We aimed to assess exposure to potentially harmful excipients for children younger than 4 years and determine if the amount exceeds the acceptable daily intake (ADI) in these patients.

Material and methods A retrospective descriptive study was conducted in neonates and children younger than 4 years of age who received oral medicines during a period of 1 year. According to the literature, propylparaben, propylene glycol, sodium benzoate, sorbitol, ethanol and sulphites were considered as potentially harmful excipients (PHE) for paediatric and neonatal patients. The estimated ADI of each excipient was also established from the literature. The different oral drugs and the total dose received was collected. The information about the amount of studied excipients was not available in the data sheet, so it was necessary for it to be provided by the pharmaceutical laboratories. Pharmaceutical composition, vaccines and enteral diets were excluded.

Results A total of 609 patients who received 98 different drugs were included. We found that 28.6% (28) of drugs contained at least one excipient studied and 26% of patients were exposed to PHE. We observed that 9 drugs included had sorbitol, 8 had propylparaben, 7 sodium benzoate, 7 propylene glycol, 4 ethanol and 1 had sulphites.

The ADI was exceeded in 26 cases of the 158 patients that had been exposed to PHE. According to these results, the ADI of sodium benzoate was exceeded in 34.6% of patients, sorbitol in 34.6%, sulphites in 11.5%, ethanol in 11.5% and propylene glycol in 7.6%. Propylparaben ADI was not exceeded in any case.

The ADI was exceeded in six drugs of the total products analysed: calcium phosphate solution, potassium bicarbonate tablets, rifampicin suspension, domperidone suspension, clonazepam and diazepam solution.

Conclusion and relevance The percentage of patients who exceeded the ADI of the PHE was low, although the ADI should not be exceeded in any case. Quantitative information about excipients should be available to health professionals in order to take into account excipient issues when selecting medicines for this vulnerable group.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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