DATA QUALITY ANALYSIS OF ADVERSE DRUG EVENTS IN A VOLUNTARY REPORTING SYSTEM

Aznar Saliente, MT (1); Roca Aznar, L (1); Herraez Robles, P (1); Bonete Sánchez, M (1); Pons Martínez, L (1); Ruiz Darbonnens, S (1).

(1) HOSPITAL SAN JUAN DE ALICANTE, PHARMACY SERVICE, Alicante, Spain

Objectives
➢ To determine the number and type of errors found in the SINEA (an electronic voluntary reporting system for adverse events (AE) in healthcare) database reports of adverse drug events (ADE), to propose improvements to reduce them, and to note the differences in the results of the raw and refined databases to skip the refining process, if possible.

Materials and methods
➢ AE reported between 1 January and 30 August 2014 were revised by a pharmacist to refine the database considering the field "describe_what_happened" as gold standard. Percent of medication errors (ME), adverse drug reactions (ADR), potential (PME) and real medication errors (RME), distribution of the effect on the patient, the impact on assistance, and the most frequently reported drugs (MFD) were compared in both raw and refined databases. Cohen's kappa (κ) statistic defining concordance was calculated.

Results

TOTAL AE REPORTED (RAW DATABASE)

![Diagram showing the distribution of AE reported in the raw database]

AE REPORTED AS REFINING PROCESS

![Bar chart showing the refinement process]

➢ 2 AE were wrongly classified as both ME and ADR, thus total percent > 100%. The "active_ingredient" field in 133 reports was empty.
➢ With refined data, the MFD was trastuzumab (20.9%), due to exhaustive notification in oncology.
➢ A mean of 1.8 ± 1.9 errors per report were detected.

Conclusions
➢ Although concordance is good, the refining process cannot be skipped as it provides quality information to implement improvements in pharmacotherapy.
➢ Data quality could be improved by reducing the number of type-in text fields and using checkboxes or drop-down lists and by increasing the staff's knowledge about ADE.

References