Electronic Supplementary Material - Drug Safety

Dose-specific adverse drug reaction identification in electronic patient records: temporal data mining in an inpatient psychiatric population

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Online results

To compare our method to the spontaneous AE report approach, we acquired all suspected AEs on 18 May 2011 that had been reported to the Danish Medicines Agency (now Danish Health and Medicines Authority) for chlorprothixene. The drug was used to treat most patients (1,688) in the study population. During post approval safety monitoring, 157 individual cases of suspected AEs had been reported for chlorprothixene, spanning a broad range of types and severity with a shift towards extreme events among the most reported compared to our results. On average 19,778 individuals collected chlorprothixene prescriptions from pharmacies in Denmark each year between 1999 and 2010 [1]. In comparison, we extracted 342 unique patient–AE pairs involving AEs that were statistically significantly associated with the drug among the 1,688 patients prescribed chlorprothixene.

Spontaneous report submissions have a tendency to preferentially address serious and severe suspected AEs. This is visible in the data where the second-most reported AE in Denmark for chlorprothixene is neuroleptic malignant syndrome (NMS), which made up 3.8% of all reported suspected AEs, only surpassed by rash. The method identified NMS occurring during chlorprothixene treatment at 0.17% relative frequency and 0.12% absolute frequency. The latter number is in line with frequencies found in the literature (0.07%-0.24%) [2].

Both the apparent underreporting and the tendency to a larger extent report serious and severe suspected effects becomes clear by comparing this single hospital's EPR system with submitted reports for chlorprothixene, introduced more than 50 years ago [3].

Online references

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