SPONTANEOUS REPORTING OF ADVERSE DRUG REACTIONS IN A SECOND LEVEL HOSPITAL: IS PHARMACOVIGILANCE WELL TARGETED?

L. Borràs Trias¹, C. Pontes², M. García Argelaguet¹, M. De Castro Juvelé, L. Raich Montiu¹, M. Gorgas Torner¹.
1Hospital de Sabadell - Institut Universitari Parc Taulí - Universitat Autònoma de Barcelona, Servei de Farmàcia, Sabadell, Spain. 2Hospital de Sabadell - Institut Universitari Parc Taulí - Universitat Autònoma de Barcelona, Unitat Farmacologia Clínica, Sabadell, Spain.

BACKGROUND
It has been repeatedly reported that up to 7% of patients have serious adverse drug reactions (ADR) during hospital admissions. Hospital-based pharmacovigilance aims to detect previously unknown serious ADR arising during differential diagnosis, with focus on special populations, but relies on spontaneous reporting by physicians.

PURPOSE
As a part of process auditing, we reviewed spontaneous ADR reports received by the Hospital Pharmacy since the introduction of an intranet-based formulary for reporting, in order to assess if the system is targeted to detect previously unknown ADR and serious ADR in special populations.

MATERIAL AND METHODS
All reports received between January 2011 and December 2013 were reviewed. The suspected drugs and whether they had regulatory requirement of additional monitoring (ie: black triangle in labelling), the seriousness of the reaction and the novelty of the clinical association (ie: absent in the product summary of product characteristics) were described.

RESULTS
There were 53,332 admissions during the period. Assuming a 7% incidence, 3,733 serious ADR were expected, but only 114 (3%) were received. Of these, 6 (5%) reports described previously unknown associations, of which 3 (2.5%) were confirmed as at least possibly related: hepatitis associated to metamizol (1) and rizatriptan (1), and leukocytoclastic vasculitis associated to tocilizumab (1).

CONCLUSION
Our audit pointed out huge infranotification, but highly focused reports: most reports were of serious events, one third involved special populations, and one fifth drugs involved with regulatory requirement of additional monitoring. Actions to improve notification are required, but the fact that 3% of the reports were relevant suggests that the system is already focused.