

DESCRIPTION OF A PHARMACOVIGILANCE PROGRAM IN A TERTIARY HOSPITAL

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Background and importance

Pharmacovigilance (PV) is a public health activity in which the clinicians are legally and medically involved.
Notification of adverse drug reactions (ADRs) is essential to ensure the safety of medications.

Aim and objectives

To describe the ADRs notified to the Regional Center of Pharmacovigilance (RPC).

Material and methods



Retrospective study → January 1992 – December 2018

PV started up in 1992 accompanied by a strong information and communication campaign.

- sex and age of patients
- total number of reported ADRs notifications
- detection method
- severity and outcome of the ADRs
- medications involved and therapeutic group Anatomical Therapeutic Chemical (ATC) classification

Data were recorded and analysed in Excel®2007

Results

During 27 years of period study, 1246 ADRs were reported (annual average: 46±2.83).

Gender	%
Men	53,6
Woman	46,4

Age (years)	%
<30	10,6
30-65	35,2
>65	54,2

Detection method	%
Minimum Database Set for hospital (MDS-H)	59,7
Voluntary notification of health staff	35,2
Hospital pharmacist (HP) during treatments validation	54,2

Severity	%
Mild	16,8
Moderate	45
Severe	38,2

Outcome of the ADRs	%
Without sequels	92,8
With sequels	6,1
Exitus	1,1

ATC classification	TOTAL	%
A: Alimentary tract and metabolism	50	3,7
B: Blood and blood forming organs	90	6,7
C: Cardiovascular system	225	16,6
D: Dermatologicals	3	0,2
G: Genito urinary system and sex hormones	13	1,0
H: Systemic hormonal preparations, excluding sex hormones and insulins	31	2,3
J: Anti-infectives for systemic use	211	15,6
L: Antineoplastic and immunomodulating agents	69	5,1
M: Musculoskeletal system	265	19,6
N: Nervous system	273	20,2
P: Antiparasitic products, insecticides and repellents	1	0,1
R: Respiratory system	23	1,7
S: Sensory organs	14	1,0
V: Various	85	6,3
TOTAL	1353	

1353 drugs were involved [(median 42 per year (IQR: 33-76.3)].

The major therapeutic groups were N(nervous system) with 20.2% and M(musculoskeletal system) 19.6%, followed by C(cardiovascular system), 16.6%, and J(anti-infectives for systemic use), 15.6%.

In 1992, 19 ADRs were notified, a value that progressively increased over the years, reaching its highest in 2003 (84 ADRs). In 2004 it decreased to 46, then remained constant (mean: 35.7±9.7), even declined to 31, the last year.

Conclusion and relevance

More than one-third of ADRs are serious, most of them recovered without sequels. Most notifications to RPC come from MDS-H, but a significant number is detected by health staff and HP. In recent years the reported ADRs has decreased, so the HP could be a essential element to develop the Pharmacovigilance Program, which is key to improving the safety of medicines by promoting relevant modifications in technical data-sheets and issuing alerts from the Spanish Agency for Medicines and Health Products.

