CPC-057

EVOLUTION OF CLINICAL TRIAL PRESCRIBING INCIDENTS

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Background:

It is essential to record incidents in clinical trials (CT) to monitor them appropriately. It is a basic tool to analyse and detect problems.

Purpose:

To analyse the development in prescription incidents recorded from 2009 to 2011, to identify and resolve quality problems, with the aim of establishing corrective actions to reduce CT problems in a process of continual improvement.

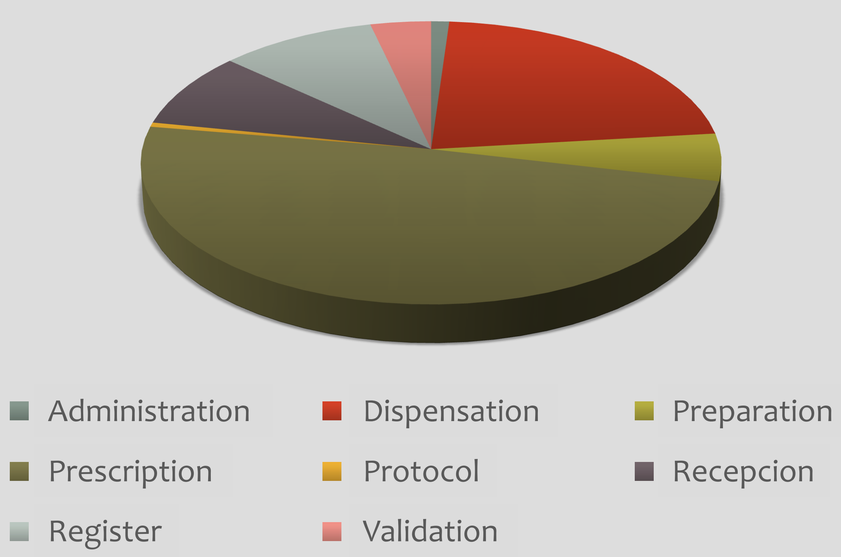
Material and Methods:

The most frequent incidents were found in the prescription phase. Data were recorded using the following items: date, person reporting, CT identification, department, professional involved, description of the problem and corrective measures. The evolution of incidents was analysed by chi square.

Results

186 events were recorded in a total of 331 CTs.

% Events by Process



% Causes of Prescribing Incidents

	Causes	2009	2010	2011
Prescription	Non specification patients included in CT	74.2%	27.1%	5.3%
	Incomplete prescription	2.6%	24.2%	31.6%
	Non adherence to study protocol	2.6%	12.2%	15.8%
	Incorrect doses	18%	18.2%	36.2%
	Other causes	2.6%	18.2%	10.5%

Evolution of Prescribing Incidents

	2009	2010	2011
Prescription	2.01 % (39/1932)	1.64 % (33/2012)	0.92 % (19/2050)

Conclusions

To manage the process as the Ethics Committee requires it is essential to have excellent communication and coordination between the pharmacy department and the other professionals involved.

Measures taken were: increased electronic prescribing, using an application specific for CT prescription and communication to researches.

The measures were effective in achieving a reduction in incidents in CT prescribing.

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