GRP010

Clinical trials management by the Hospital Pharmacy Department: Analysis of events registered

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OBJETIVE

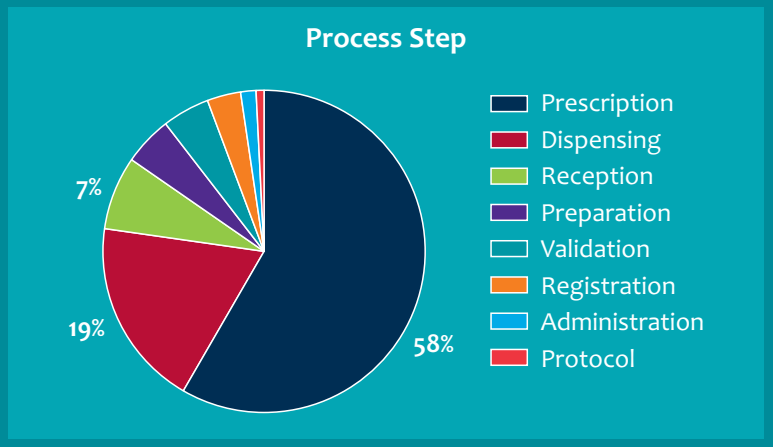
To analyse early identification and resolution of Clinical Trial (CT) problems in order to improve our working procedures within a quality system.

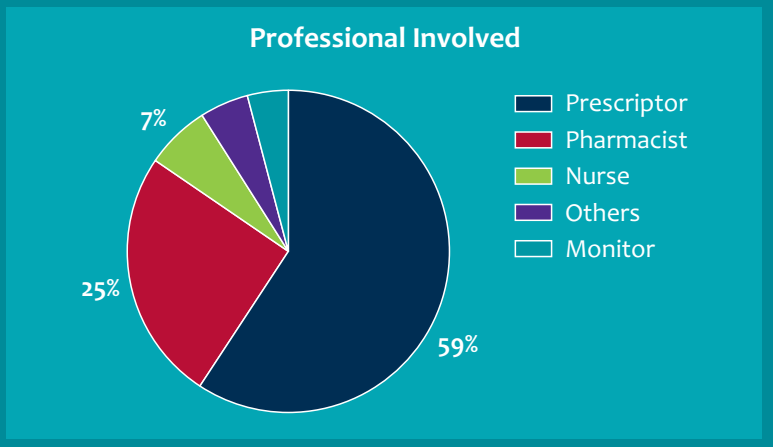
METHODS

Analized items: date, reported person, CT identification, investigational department, process step (protocol, reception, storage, prescription, validation, preparation, dispensing, administration, return, registration), professional involved, problem description and corrective measures recorded during 2009-2010.

RESULTS

174 CT carried out, 123 incidents registered in 3927 prescriptions.





EVENTS	FRECUENCY
Prescription process	**1.8%**
No specification that the patient was included in aCT	54%
Incomplete prescription	22%
Non-adherence to the study protocol	21%
Dispensing process	**0.6%**
Incorrect number of units dispensed	30%
Omission of information to patients	26%
Dispensation of commercial medication intead of research samples	13%
Non compliances of administrative requirements	13%
Reception process	**0.2%**
Discrepancies in delivery note and real data	33%
Delivery problems	33%

DISCUSSION

The improvement opportunities identified after the analysis of incidents are to expand e-prescribing, remember and promote the standards of dispensing to the staff involved, highlighting properly dispensing requirements and to report on erroneous receptions to staff involved (monitor, sponsor, carrier).

CONCLUSIONS

Knowledge of errors makes possible to determine the elements that reveal weaknesses and to establish measures to control and reduce them, increasing the efficiency of the process.

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