CPC031

Assessment of the information on investigational oral treatment provided to patients in clinical trials

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BACKGROUND AND PURPOSE

Clinical trials sponsors (CTS) provide to patient information about objective, description of the treatment, alternatives and other related questions .

Objective: to review the information provided by the CTS and assess the need to develop a complementary information form.

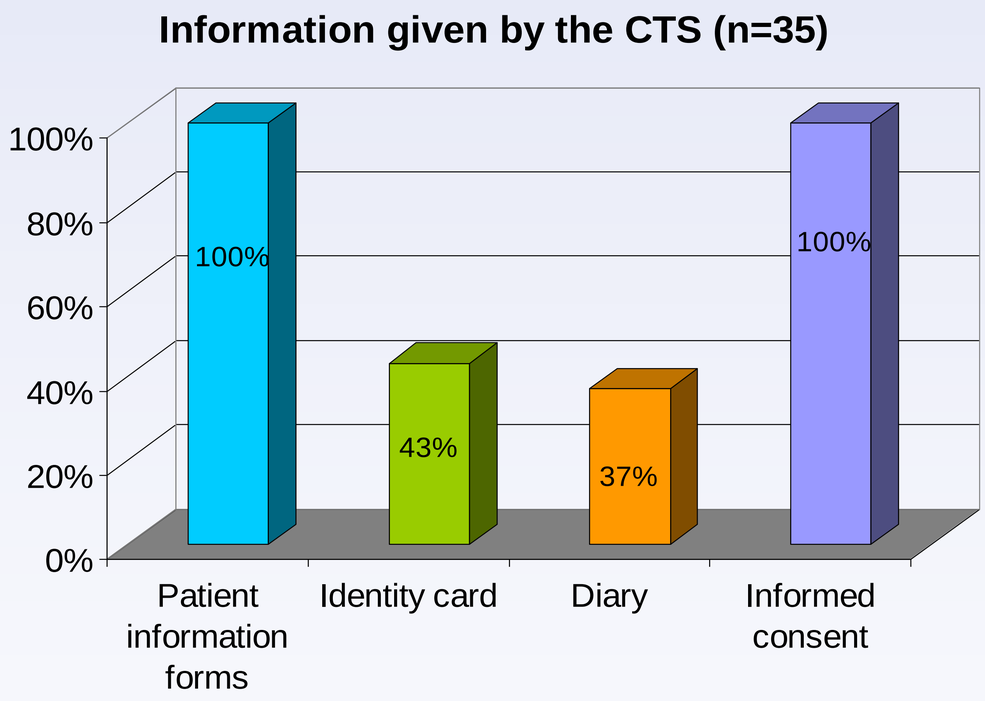
MATERIAL AND METHODS

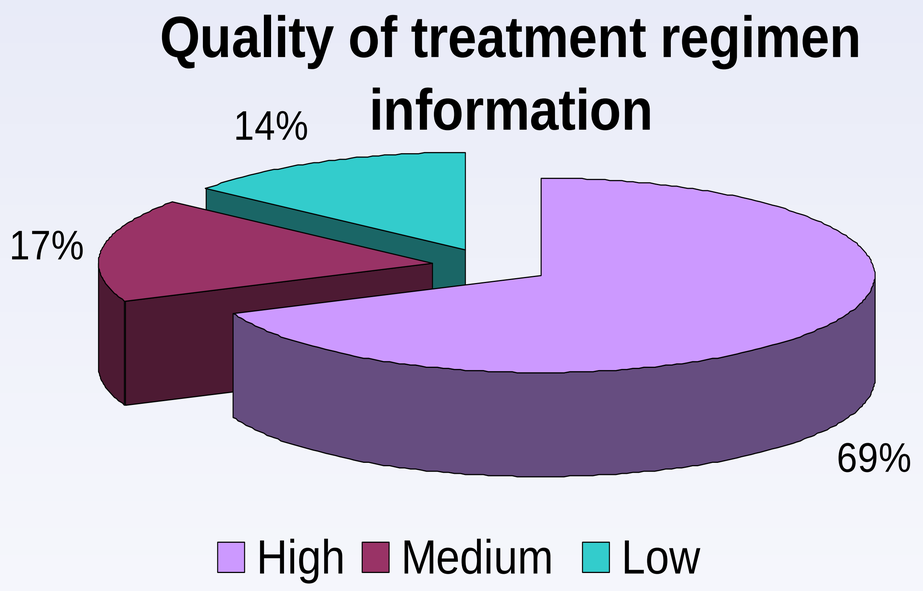
A cross-sectional, descriptive study was conducted during March 2011. At the time of analysis there were 104 active trials. In 35 (33.7%) the pharmacist dispensed to patient the investigational oral drug. The informed consent, patient information forms (PIF) and patient diaries were reviewed. In these documents quality of following items was checked:

- Treatment regimen: high (dose description, allowed delays and route of administration), medium (only referred to dose) and low (no references or details about treatment regimen).
- Adverse events (AE): information present or not.
- Interactions with the study drug. Documents were divided in those that were detailed and those which do not mention any information.

RESULTS

Regarding to the documents given by the CTS and the information contained in these documents, it was found that:





Information contained in PIF (n=35)

	Included	No included
Treatment regimen	35	0
Adverse events	35	0
Interactions	19	14

CONCLUSIONS

The information provided by CTS is in some cases deficient or confusing. For this reason the clinical trials department of Pharmacy Service decided to make a complementary information form which will be given to patient. This form will contain: simplified information about dose schedule, route of administration, conservation and how to contact with pharmacy.

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