

A Carmona¹; A Cransac¹; J Paris¹; C Brun¹; L Porcher¹; M Boulin¹; C Pernot¹
¹Pharmacie, Unité de Pharmacotechnie et Essais Cliniques, CHU Dijon Bourgogne
 14 rue Paul Gaffarel, 21000 DIJON

OBJECTIVES

According to the Code of Public Health, the **pharmacist** advises and informs the patient to ensure the right use and high drug adherence. In Clinical Trials (CT), Investigational Medicinal Products (IMP) are dispensed by pharmacy department.

A copy of the **prescription** is given to the patients in ambulatory: it's a support of information for the patient available at any time at home. In our hospital, prescriptions for CT are usually provided by the sponsor.

The purpose of this work is to evaluate **information about IMP** on the prescriptions provided by the **sponsors** and to propose areas for improvement.

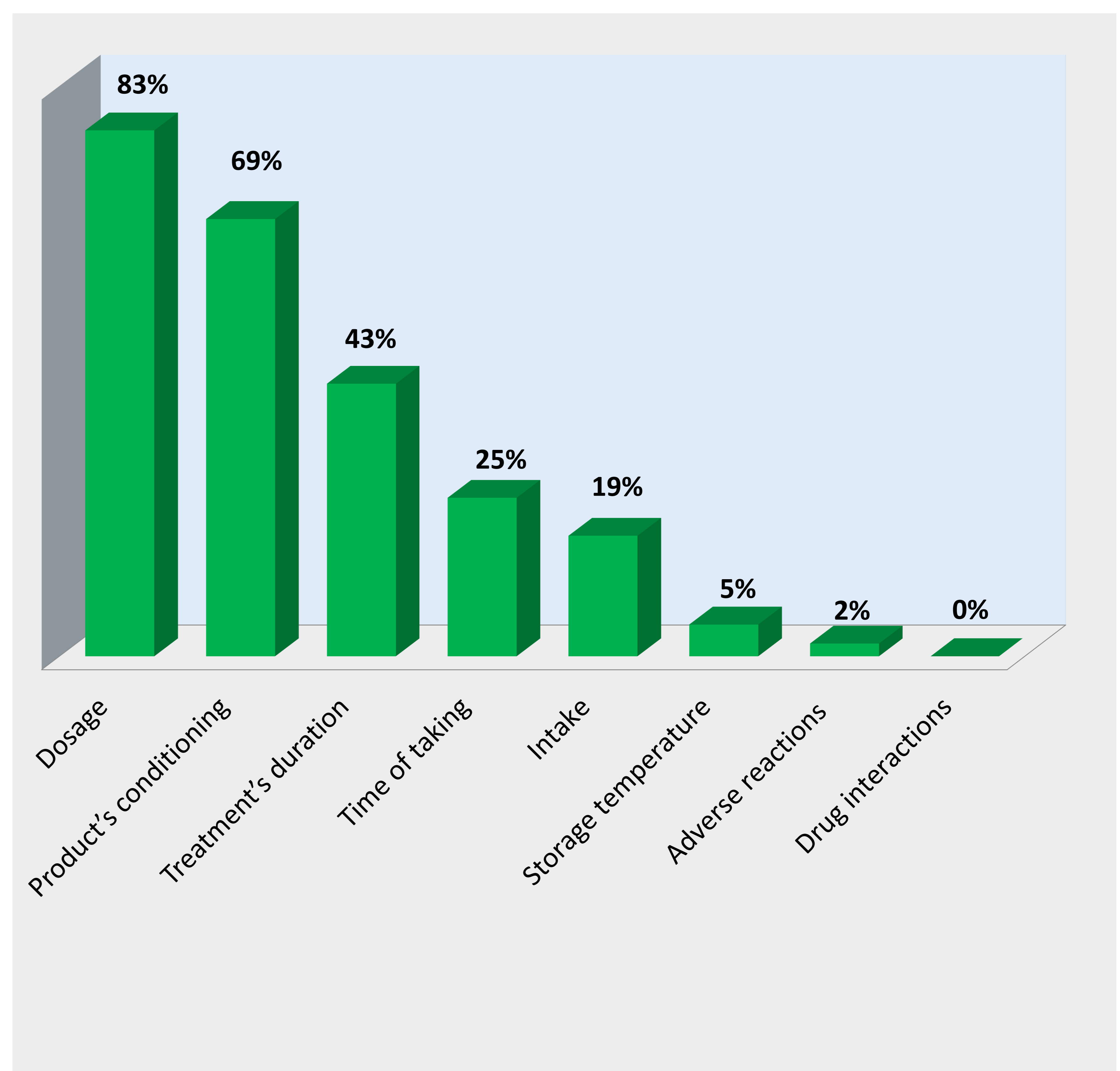
METHODS

All the CTs with **at least one IMP** was taken at home and opened in the pharmacy department of a university hospital on 1 January 2018 were included in this retrospective study. A check list of **8 criteria** deemed essential to inform the patient regarding his treatment was created in accordance with the regulations.

Etat des lieux des conseils pharmaceutiques sur une ordonnance dans les essais cliniques	C.H.U de DIJON Pharmacie du CHU de DIJON	
Formulaire de recueil		
N° _____	Date: _____	Service: _____
Evalueur: _____		
Essais clinique		
Nom de l'essai clinique: _____		
Investigateur: _____		
Promoteur: _____		
Produit(s) à l'étude sur l'ordonnance		
Noms	Voies d'administration	
TRAITEMENT : Chimiothérapies orales ? : <input type="checkbox"/> OUI <input type="checkbox"/> NON		
Présence de conseils sur l'ordonnance : <input type="checkbox"/> OUI <input type="checkbox"/> NON		
Type de conseils :		
<input type="checkbox"/> Conditionnement des UT (gâule, comprimé...)		
<input type="checkbox"/> Température de conservation		
<input type="checkbox"/> Posologie		
<input type="checkbox"/> Moment de prise (horaire)		
<input type="checkbox"/> Modalités de prise (par rapport aux repas, si oublié, manipulation...)		
<input type="checkbox"/> Durée		
<input type="checkbox"/> Conduite à tenir si effet indésirable		
<input type="checkbox"/> Interactions avec produits non médicamenteux		
<input type="checkbox"/> Autres :		
Autre support papier remis au patient ? : <input type="checkbox"/> OUI <input type="checkbox"/> NON		
Si oui, de quel type ? :		

RESULTS

Proportion of prescriptions containing each information



- 93 clinical trial files were analyzed (35% were institutional study)
- 11% of the prescriptions haven't any pharmaceutical advice
- 88% of IMP are oral medications of which 30% are chemotherapy

DISCUSSION AND CONCLUSION

The most frequent information on prescriptions is the **dosage** and the **packaging** of the IMP. At the other end, information on what to do in case of **adverse event** and **drug interactions** are rare or non-existent. The **pharmacist** has an important and essential role to dispense pharmaceutical advice for CT (1). A collaboration between services and pharmacy is planned in order to establish a **standard prescription** for CTs with specific information. Improving the quality of prescription information will optimize the safety of IMP taking.

(1) J.A. Schoenenberger *et al.* Assessment of the information on investigational oral treatment provided to patients in clinical trials. *European Journal of Hospital Pharmacy* 2012, 19 (2)230-231.

