REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-023 THE ROLE OF INSTITUTIONAL REVIEW BOARDS, AND HOSPITAL PHARMACISTS AS MEMBERS, IN THE INFORMED CONSENT PROCESS IN CLINICAL RESEARCH: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and importance It is the responsibility of institutional review boards (IRBs) and hospital pharmacists, as members of these boards, to review a research proposal and ensure that adequate informed consent procedures are implemented in an ethical way, promoting participant autonomy and protecting them from potential harm. In this context, informed consent forms (ICFs) have become increasingly complex and difficult for patients to understand.
Aim and objectives To analyse non-approval of clinical research by IRBs, related to deficiencies found in the ICFs. Secondary outcomes were type of objections in terms of readability, length, description of study purpose, design, expected benefits and foreseeable risks. Other ethical and legal aspects, such as voluntary agreement to participate, right to withdraw, biological sample management and access to personal data were also analysed.
Material and methods This was a retrospective observational study of the clinical studies evaluated by the IRB in a tertiary hospital. We evaluated the IRB resolutions of all clinical studies over 4 years, including interventional studies (clinical trials) and non-interventional research assessed by the IRB where a hospital pharmacist was a member of the board. The committee's decisions on approval were registered in the minutes of the meetings. The pharmacists reviewed the minutes, evaluating the final opinion of the committee (approval/non-approval of the study) in the first review.
Results A total of 91 sets of minutes, corresponding to the IRB meetings over 4 years, were analysed. In these meetings, 1858 clinical trials were evaluated (1057 clinical trials and 801 non-interventional studies). Of these, 1558 required informed consent for participation (83.9%, 95% CI 82.1–85.5) and 987 were not approved at first review due to deficiencies detected in the ICF (63.3%, 95% CI 60.9–65.7). The main reasons for non-approval were unreadability (11.7%), inadequate information given about access to personal data rights (9.2%), biological sample management (7.8%) and expected benefits (7.6%).
Conclusion and relevance There was a high proportion of deficiencies in the ICFs for clinical research. They were an important reason for non-approval of protocols evaluated by IRBs. Taken together, there are three fundamental weaknesses in ICFs where IRBs in hospitals play a key role: improving their readability, adapting them to regulations concerning data protection or biological sample management, and avoiding misleading information concerning enrolment.

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National Poster Prize Winners

NP-001 IMPACT OF AN ORAL NUTRITION PROTOCOL IN PATIENTS TREATED WITH ELECTIVE RADICAL CYSTECTOMY: A LONG TERM FOLLOW-UP

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Background and importance Before we implemented an oral nutrition protocol, parenteral nutrition (PN) was standard of care after elective radical cystectomy (RC) patients in our hospital. PN is expensive, with often metabolic and infectious complications.
Aim and objectives The main objective of this study was to explore the impact of the introduction of an oral nutrition protocol on catheter-related bloodstream infection (CRBSI) incidence. Besides, length of stay and parenteral nutrition (PN) associated costs were compared.
Materials and methods In this large retrospective case-control study, before (PN group) and after the implementation of the oral nutrition protocol (since March 2010), two cohorts of 549 patients who underwent an elective RC were included. A central venous catheter was present in every patient, which is standard of care. The incidence of a CRBSI, the length of stay and PN associated costs were compared.
Results In both the control (June 2000–March 2010) and the case (March 2010–December 2017) group, an equal number of 549 patients were included. CRBSI was reduced from 22 (4%) to 10 (1.8%) ($p=0.031$).

The median length of stay between both groups, 20 [17 – 25] days before vs. 17 [14 – 21] days after the implementation of the oral nutrition protocol, also differed significantly ($p<0.001$).

Implementing the oral nutrition protocol resulted in a parenteral nutrition associated cost saving of € 470 per patient.
Conclusion and relevance This large follow-up study showed that an oral nutrition protocol is associated with a reduction in CRBSI. Besides, postponing PN in favour of oral nutrition enhances recovery and is associated with cost savings. In conclusion, we believe that the clinically relevant results of our study are confirming that oral nutrition should be standard of care in elective regular RC patients.

NP-002 MEDICATION SAFETY IN PATIENTS TREATED WITH ORAL ANTITUMOR AGENTS: A PROSPECTIVE, RANDOMISED INVESTIGATION TO IMPROVE PATIENT SAFETY AND WELL-BEING BY INTENSIFIED CLINICAL PHARMACEUTICAL/PHARMACOLOGICAL CARE

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Background and importance During the last few years, prescription rates of oral anticancer drugs have increased rapidly. Because of the independent intake of these highly complex