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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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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

therapies, a close patient guidance and management is essential to prevent treatment failure because of drug-drug or drug-food interactions, side effects or non-adherence.

Aim and objectives The aim of this study is to investigate whether integrating a clinical pharmacist/clinical pharmacologist into a multi-professional care team can improve patients' safety, knowledge and well-being.

Materials and methods For this purpose, 200 patients will be randomised. While the intervention group will receive an intensive care program with information material and side effect management, the control group will only receive routine clinical care. Primary outcome parameters are the number of drug related problems (medication errors and side effects) regarding the oral anticancer drug and patient satisfaction (TSQM questionnaire). Further outcome parameters will include, for example, the number of serious side effects and hospitalisation rates.

Results For this interim analysis, 100 patients were included. In the intervention group the number of drug related problems regarding the oral anticancer treatment was reduced (7.38 vs. 4.75 per patient; $p<0.05$) and patient satisfaction was significantly increased ($p<0.01$). The intervention group showed a lower rate of serious side effects and was less frequently admitted to a hospital.

Conclusion and relevance The high rate of drug related problems in this patient population indicates that cancer patients treated with oral anticancer drugs must be considered as a high-risk patient group. Early intervention can reduce serious side effects and increases patients' satisfaction. The integration of a clinical pharmacist/clinical pharmacologist in a multi-professional care team increases medication safety in patients treated with oral anticancer drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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NP-003 STEADY-STATE PHARMACOKINETICS AND EARLY SAFETY DATA IN HIV-INFECTED AFRICAN CHILDREN WEIGHING ≥25 KG AFTER SWITCHING TO 50 MG FILM-COATED DOLUTEGRAVIR TABLETS IN THE ODYSSEY TRIAL

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Background and importance ODYSSEY is an ongoing international randomised trial evaluating dolutegravir (DTG)-based antiretroviral therapy (ART) versus standard-of-care in HIV-infected children starting first- or second-line ART. Pediatric DTG film-coated tablets (FCTs) of 10 mg and 25 mg are unavailable in low- and middle income countries (LMIC) were most HIV-infected children live. Adult DTG 50mg FTCs are produced by generic manufacturers at low-cost, are well-tolerated, and already available in many high- and LMICs.

Aim and objectives Within ODYSSEY pharmacokinetic (PK) substudies were undertaken to assess PK and safety data for a simplified paediatric DTG dosing approach using WHO weight bands (WBs) 25 to <30 kg and 30 to <40 kg and once daily 50 mg adult DTG doses.

Materials and methods Steady-state 24-hour PK curves were constructed from data in children (≥3 h fasted) observed taking current EMA-approved DTG doses of 25 mg and 35 mg (10 mg+25 mg FCTs)) in 25-<30 kg and 30-<40 kg WBs, respectively. After all children switched to single daily 50 mg DTG tablet, a second 24 h PK curve was constructed. We aimed to achieve DTG exposures comparable to historical adult data for DTG 50 mg FCTs QD taken under fasted conditions (geometric mean (GM): C_{trough}0.83 mg/L, $AUC_{0\text{-}24h}$43.4 h*mg/L, C_{max}3.34 mg/L). Additionally, results were compared to PK data for DTG 50mg BID in adults (GM ranges: C_{trough}2.41 to 2.72 mg/L, $AUC_{0\text{-}24h}$93.4 to 92.7 h*mg/L, C_{max}5.41 to 5.55 mg/L). Safety was evaluated after switch to the 50mg dose at 2, 4 and 12 weeks and then every 12 weeks.

Results 28 black-African children (52 PK profiles) from Uganda and Zimbabwe (61% male) with a median (range) age of 11.0(7.5–17.9) years old were included. For children weighing 25-<30 kg on DTG 25 mg (17 profiles) GM with coefficient of variation (CV%) for C_{trough} and $AUC_{0\text{-}24h}$ was 0.39(48) mg/L and 33.1(23) h*mg/L, respectively, and after switch to DTG 50 mg (16 profiles) values were 0.77(43) mg/L and 58.6(28) h*mg/L, respectively. For children weighing 30-<40 kg on DTG 35 mg (9 profiles), C_{trough} and $AUC_{0\text{-}24h}$ were 0.46(63) mg/L and 40.3(35) h*mg/L, and after switch to DTG 50 mg (10 profiles) values 0.63(49) mg/L and 53.5(32) h*mg/L, respectively. The 50 mg dose resulted in C_{max} values of 5.41(25) mg/L and 5.22(25) mg/L in WB 25-<30 kg and 30-<40 kg, respectively, which did not exceed historical C_{max} values for adults on 50 mg BID. After a median (IQR) follow-up of 30(12–30) weeks on 50 mg DTG 3/28(11%) children had grade 3 or 4 adverse events (one SAE; cryptococcal meningitis) and all were considered unrelated to DTG.

Conclusions and relevance Adult 50 mg FCT once-daily dolutegravir provides appropriate PK profiles in children ≥25 kg, with no safety signal, allowing practical dosing and rapid access to dolutegravir. WHO has released new pediatric dosing guidelines in response to these results.

NP-004 INITIATION OF A CLINICAL PHARMACIST LED, PROSPECTIVE AUDIT ON ANTIBIOTIC PRESCRIBING

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Background and importance A pharmacist led, prospective audit on antibiotic prescribing was introduced on three hospital wards, as an element of the local, institutional antibiotic stewardship program (ASP).

Aim and objectives Our aims were to document and evaluate each antibiotic prescription and therapy based on the antimicrobial stewardship program recommendations and to give feedback to prescribers on their compliance to ASP guidelines.

Material and methods A paper-based audit form was prepared. Patient data, documentation of allergies, indication of the therapy and circumstances of microbiological testing were