5. Maksoud E, *et al.* Population Pharmacokinetics of Cefotaxime and Dosage Recommendations in Children with Sickle Cell Disease. *Antimicrob Agents Chemother.* 2018;**62**: e00637–1.

Disclosure(s) Nothing to disclose

P29 A SMARTPHONE APPLICATION TO MONITOR NAUSEA IN PEDIATRIC CANCER PATIENTS DURING CHEMOTHERAPY

^{1,2}A Eliassen*, ³MK Abildtoldt, ³NS Krogh, ²JS Brok, ²R Mathiasen, ²K Schmiegelow, ¹KP Dalhoff. ¹Department of Clinical Pharmacology, Bispebjerg and Frederiksberg University Hospital; ²Department of Pediatrics and Adolescent Medicine, University Hospital Rigshospitalet; ³ZiteLab Aps, Copenhagen, Denmark

10.1136/archdischild-2019-esdppp.67

Background Nausea is a common and distressing side effect for children in chemotherapy. Antiemetic recommendations are based on limited literature and prospective evaluation of antiemetic efficacy is required. Smartphone applications (apps) may collect patient-reported outcomes with precision and effectiveness¹. We developed a smartphone app to track nausea in pediatric cancer patients during chemotherapy.

Methods Medical researchers, pediatric oncologists and software engineers worked synergistically in the development. We translated the validated Pediatric Nausea Assessment Tool to score nausea severity². We conducted three rounds of patient-feedback and modification.

Results The app has a definition module where the child centers the attention to the concept of nausea. The child can then express nausea severity with four faces and the child's own definition of nausea is incorporated in the question². The app includes a notification system to ensure high response rates. All participants felt that the app was user-friendly, intuitive and that time spent was acceptable.

Conclusion The app is a user-friendly tool to assess nausea in pediatric cancer patients that can ease future pediatric antiemetic trials.

REFERENCES

1. Stone AA, Shiffman S, Schwartz JE, *et al.* Patient compliance with paper and electronic diaries. *Control Clin Trials* 2003 Apr;**24**(2):182–99.
2. Dupuis LL, Taddio A, Kerr EN, *et al.* Development and validation of the pediatric nausea assessment tool for use in children receiving antineoplastic agents. *Pharmacotherapy* 2006;**26**:1221–31.

Disclosure(s) Nothing to disclose

P30 LIMITED SAMPLING STRATEGIES TO PREDICT VALGANCICLOVIR EXPOSURE IN KIDNEY TRANSPLANTED CHILDREN

N Benyoub, A Facchin, S Magreault, E Jacqz-Aigrain, V Elie*. *Pediatric Pharmacology and Pharmacogenetics, Hôpital Robert Debré, APHP, Paris, France*

10.1136/archdischild-2019-esdppp.68

Background Ganciclovir and its pro-drug, valganciclovir, are anti-viral drugs used in cytomegalovirus infections treatment in kidney transplanted children. Both present a high pharmacokinetic variability requiring dosage individualization and Therapeutic Drug Monitoring to ensure optimal therapeutic exposure. This retrospective monocentric study aimed to develop a Limited Sampling Strategy (LSS) predicting Area

Under the Curve (AUC_{0-24h}) reducing the number of blood samples to improve and facilitate kidney transplanted children medical care.

Methods Pediatric kidney transplanted children treated with valganciclovir were included. Rich pharmacokinetic data from ganciclovir plasmatic dosages (sampling times at 0h, 1h, 2h, 4h, 8h, 12 h and 24 h) were collected between February 2005 and November 2018. Ganciclovir exposures at steady-state (AUC_{0-24h}) were calculated using the trapezoidal method. The LSS was developed using a multilinear regression approach to predict AUC_{0-24h}. The overall patients population was divided into two groups for model development and validation purposes.

Results 129 patients were included: 46 girls and 83 boys, mean age at transplantation was 11.3years ± 5.1. Multilinear regression models were developed on 85 pharmacokinetic profiles (85 patients, mean AUC_{0-24h}=64µg.h/mL ± 27, creatinine clearance=72.4 mL/min per 1.73 m²) and validated on an independent group of 73 pharmacokinetic profiles (44 patients). Regressions based on samples collected at 0, 2, 4 h (R=0.946) or 0, 2, 8 h (R=0.968) presented the best AUC_{0-24h} predictive performances (RMSE=7.5 and 6.6, MAE=5.7 and 4.8 respectively) with an average difference between reference and predicted AUC_{0-24h} of -0.52 and 0.67µg.h/mL respectively.

Conclusions To date, this is the largest cohort of valganciclovir treated pediatric transplanted children used to develop a LSS. This LSS allows to accurately predict ganciclovir AUC_{0-24h} in pediatric transplanted patients using 3 pharmacokinetic blood samples at 0h, 2h, and 4 h post-dose. Beside other Bayesian estimators developed in the literature, this multilinear regression can be easily implemented into daily practice facilitating patients care.

Disclosure(s) Nothing to disclose

P31 NO INTERACTION BETWEEN DOXAPRAM AND CAFFEINE FOR THE TREATMENT OF PRETERM NEONATES WITH APNEA

¹A Engbers*, ¹N Dia, ^{1,2}S Völler, ^{1,3}CAJ Knibbe, ⁴IKM Reiss, ⁵BCP Koch, ^{4,5}RB Flint, ⁴SHP Simons. ¹Systems Biomedicine and Pharmacology; ²BioTherapeutics, Leiden Academic Centre for Drug Research, Leiden University, Leiden; ³Department of Clinical Pharmacy, St Antonius Hospital, Nieuwegein; ⁴Department of Paediatrics, Division of Neonatology, Erasmus MC – Sophia Children's Hospital; ⁵Department of Hospital Pharmacy, Erasmus Medical Center, Rotterdam, The Netherlands

10.1136/archdischild-2019-esdppp.69

Background In preterm neonates with apneas, co-administration with doxapram is often initiated in case of inadequate response to caffeine alone. While doxapram is exclusively registered for adults, there is limited information on its use in preterm infants. To examine whether the observed effects of doxapram are actually due to doxapram itself, and not a pharmacokinetic interaction between both respiratory stimulants, we studied the pharmacokinetics (PK) of caffeine in a population of preterm neonates receiving both caffeine and doxapram.

Methods Caffeine concentrations from patients in the DINO study (NCT02421068) who received both caffeine and doxapram were analyzed using NONMEM V7.3. A PK model of caffeine in preterm neonates was used as a basis to estimate the PK parameters of caffeine when co-administered with doxapram with F fixed to 1 and k_a fixed to 1.48 h⁻¹.¹ The

results of the current study were compared to those of the reference population published by Charles et al.¹

Results In 15 preterm infants 58 samples were collected in which caffeine plasma levels were determined. Median gestational age (GA) was 26.3 (range 24–28) weeks, postnatal age (PNA) was 25 (0–63) days and current weight was 1100 (600–2140) grams. Caffeine CL and V_d for an individual with a PNA of 12 days were estimated 0.2 L/h/70kg (RSE 28%) and 68.2 L/70kg (RSE 73%), respectively. Maturation of CL was best described by a power function with an exponent of 0.404 (RSE 89%). These results seem in good agreement with the reference population of preterm neonates receiving caffeine without doxapram with values of 0.167 L/kg/70 kg, 58.6 L/70kg and 0.358.¹

Conclusion In this pharmacokinetic study in preterm neonates receiving both caffeine and doxapram, we found similar values for CL, V_d and maturation of CL with PNA compared to literature values obtained in preterm neonates receiving caffeine alone.

REFERENCES

1. BG C. et al. Caffeine citrate treatment for extremely premature infants with apnea: population pharmacokinetics, absolute bioavailability, and implications for therapeutic drug monitoring. *Ther. Drug Monit* 2008;**30**:709–716.

Disclosure(s) Nothing to disclose

P32

DEPICTION OF HAEMATOLOGICAL AND BIOCHEMICAL LABORATORY NORMAL REFERENCE VALUES IN A EUROPEAN MULTICENTRE PAEDIATRIC TRIAL

S Farahani*, E Feles, BB Burckhardt, S Laeer, on behalf of the LENA consortium. *Institute of Clinical Pharmacy and Pharmacotherapy, Heinrich Heine University, Dusseldorf, Germany*

10.1136/archdischild-2019-esdppp.70

Background The European multicentre paediatric trials for the drug development programme of LENA (FP7 Grant agreement No. 602295); 'Labeling of Enalapril from Neonates up to Adolescents' require the determination of laboratory safety parameters. It was anticipated that the laboratory normal reference values and age range classifications vary depending on the clinical site. Thus, the objective was a seamless and clear depiction of the laboratory parameters to allow an adequate subsequent analysis of data.

Methods Fourteen haematological and biochemical safety parameters plus the biomarker N-terminal pro-brain natriuretic peptide were considered. The laboratory normal reference values received from eight clinical sites were screened on data gaps, uncertainties, misclassifications and overlap of age range classifications. These aspects were revised. If further data were necessary for clarification the responsible person of the respective laboratory was contacted by email or telephone.

Results Data gaps and uncertainties of the laboratory normal reference values such as missing data for one sex, missing data for an age range classification, missing data for a parameter or overlap of age range classification were identified. All issues were solved by communication with the sites. Each laboratory parameter was categorized in between 1 and 23 age range classifications between an age from birth to 4744 days depending on the classification of the clinical site.

Furthermore, up to 4 various units were recorded per laboratory parameter and subsequently harmonised into one unit.

Conclusion The developed seamless depiction of the laboratory parameters will allow the assessment and classification of the paediatric trial data and are essential for the adequate subsequent analysis.

Disclosure(s) Samieh Farahani, Elisabeth Feles, Bjoern B. Burckhardt, Stephanie Laeer declare that there is no conflict of interest. The research leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007–2013) under grand agreement n°602295 (LENA)

P33

EFFECTIVENESS OF OSCES IN TRAINING GERMAN PHARMACY STUDENTS IN CONSULTATION ON SELF-MEDICATION – A RANDOMISED CONTROLLED INVESTIGATION

¹I Farahani*, ²A Laven, ¹S Farahani, ¹MA Deters, ¹M Feickert, ¹FK Suessenbach, ³H Schwender, ¹S Laeer. ¹*Institute of Clinical Pharmacy and Pharmacotherapy, Heinrich Heine University, Dusseldorf;* ²*Pharmabrain Research and Training Center, Berlin;* ³*Mathematical Institute, Heinrich Heine University, Dusseldorf, Germany*

10.1136/archdischild-2019-esdppp.71

Background In Germany 37.1% of dispensed medicinal products were intended to use in self-medication in 2017.¹ An investigation showed that 25.2% of children and adolescents used self-medication in Germany.² Hence, pharmacists' education needs to include training for competence in consultation.³ A modern method to train this competence is the use of OSCEs (Objective Structured Clinical Examinations). The aim of this study was to assess whether the use of OSCEs in pharmacy students to train the consultation performance on self-medication is more effective than a conservative teaching method.

Methods This randomised controlled investigation was conducted in a pre-post-design with pre-OSCEs before training and post-OSCEs after training in each group. Clinical skills at baseline and after the training were measured. Forty students in their last year of pharmacy studies were randomised into a control and an intervention group. The control group attended a lecture on self-medication and the intervention group had additionally to the lecture one hour of OSCEs for training purpose. An analytical checklist was used for measuring consultation skills and a global rating scale for assessing communication skills.

Results Complete data was received from 30 students (n=16 intervention group, n=14 control group). Consultation skills improved significantly (analytical checklist: 19.88% ± 10.95% intervention group vs. 9.29% ± 10.89% control group, p<0.05). However, the communication skills (global rating scale: 20.83% ± 24.33% in the intervention group vs. 11.90% ± 17.12% in the control group, p= 0.380) did not improve significantly during the one-hour training period.

Conclusion OSCEs for training purpose are an effective method to convey pharmacy students consultation skills in self-medication. However, communication skills need more training. Based on these results OSCEs on self-medication for the paediatric population should be investigated. This is relevant due to the frequency of self-medication in the paediatric population.