renally cleared drugs based on eGFR may not be reliable in this patient population.

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P104 PHARMACOLOGIC DIFFERENCES OF ADALIMUMAB, INFlixIMAB AND ETANERCEPT: DO WE NEED SPECIFIC VACCINATION RECOMMENDATIONS FOR PRENATALLY EXPOSED INFANTS?

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Background In pregnancy adalimumab (ADA) and infliximab (IFX) should preferentially be stopped at gestational week 20 and etanercept (ETN) at weeks 30–32¹ because of their steadily increased transplacental transfer during the late second and third trimester. Pregnant women with chronic inflammatory diseases are often treated throughout their entire pregnancy to prevent negative impact on pregnancy outcomes from the disease. Therefore, more infants are born with prenatal exposure and the question arises if and when live vaccines can be administered safely.

Methods We reviewed pharmacologic properties of ADA, IFX and ETN with regards to prenatal exposure and vaccine recommendations.

Results IFX is a chimeric and ADA a human anti-TNF-alpha antibody. Both have high binding affinity to the neonatal Fc receptor (FcRn).² ETN is a TNF-alpha receptor fusion protein with a 5–10 fold lower binding affinity to the FcRn compared with IFX/ADA.²

At delivery neonatal drug concentrations compared with maternal ones seem to be higher in prenatally exposed infants to IFX^{3–5} (median ratio of 1.97) and ADA (median ratio of 1.21),³ whereas neonatal ETN concentrations are lower.^{6,7} The mean time to drug clearance in IFX or ADA exposed infants is 7.3 months and 4 months, respectively.³ Drug concentrations are undetectable for IFX or ADA after 12 and 9 months of life, respectively.³ In infants exposed throughout the entire pregnancy ETN is undetectable after 3 months.⁷

Infants exposed to ADA, IFX and ETN before gestational week 22 can follow the normal vaccination schedule including live vaccines,¹ whereas live vaccines in infants exposed in the late second and third trimester should be avoided for 6–12 months of life.^{1,3}

Conclusion Pharmacologic differences of ADA, ETN and IFX require specific live vaccine recommendations for infants exposed prenatally to these drugs.

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P105 AMBULATORY STUDY CENTER AT THE UNIVERSITY OF BASEL CHILDREN'S HOSPITAL (UKBB)

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Background Many drugs authorized in Europe and the United States are inadequately studied in children. SwissPedNet Funding has boosted the development of specialized and professional pediatric centers for clinical studies in Switzerland tasked with executing compliant, reliable and family-centered clinical research. The University of Basel Children's Hospital (UKBB) is one of the pediatric clinical study centers.

Methods The Department for Clinical Research in Basel consists of the study center for adults at University Hospital Basel (USB) and the Ambulatory Study Center (ASZ) focusing on pediatric studies at the UKBB. The latter was established in 2015, and consists of a specialized team, including a medical director, medical coordinator, medical specialists in pediatrics as well as a team of study nurses.

The ASZ supports and promotes clinical studies with and for infants and children for external and internal sponsors in various therapeutic areas such as oncology, cardiology, pneumology, nephrology, neuropsychiatry, orthopaedics and infectious diseases. The full range of activities for executing the approved clinical study protocol can be offered, including planning, implementation, budgeting, coordinating, monitoring and archiving as well as collaboration with all required hospital departments.

Results Up to now, the ASZ has enrolled around 600 children in clinical trials, with 6 studies completed and 12 studies ongoing. A comprehensive Quality Management system was established and SOPs were jointly created with the adult study center. A digital clinical study request form is available for sponsors via the website.

Conclusion We see an increased demand for pediatric clinical studies across all age ranges and therapeutic areas. We envision a center of excellence with a pool of fully trained study nurses to accommodate and centrally organize all pediatric studies in the UKBB. Parent engagement and patient inclusion is one critical step to further improving healthcare for pediatric patients through highest quality clinical research.