5 THE PERCEIVED BARRIERS AND FACILITATORS FOR MODEL-INFORMED DOSING IN PREGNANCY: A QUALITATIVE STAKEHOLDER ANALYSIS

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Introduction The lack of evidence for drug dosing in pregnancy represents a large unmet need for pregnant women and their unborn child. This study examines Dutch stakeholders' perceptions of model-informed dosing in pregnancy as part of an effort to build a model-informed pregnancy formulary (MIPF).

Methods Online focus groups and individual interviews were conducted with health care practitioners (HCPs) from various specialties (gynecology, pharmacy, general medicine, midwifery and other medical specialties) and with currently or recently pregnant women. The perceived barriers and facilitators for implementing a MIPF were identified using a hybrid thematic analysis.

Results 30 HCPs and 10 pregnant women participated in nine focus groups and three interviews. The awareness of pharmacokinetic changes in pregnancy varied across focus group participants. While a majority of HCPs and pregnant women found a MIPF to be a relevant innovation, several participants across both groups indicated that the lack of information on fetal safety constituted another important gap to address. The information needs of HCPs in order to be willing to apply model-informed dosing recommendations varied. A majority of participants indicated that they preferred model predictions to be clinically verified for the concerned drug. HCPs expressed different preferences with regards to the most appropriate website for publishing model-informed dosing advice. Several pregnant women indicated that they wanted to be informed on the evidence behind model-informed dosing recommendations.

Conclusions Stakeholders' views on the barriers and facilitators for relying on model-informed dosing in pregnancy will be further investigated through an online survey and will inform the design of a MIPF.

6 PBPK MODEL-INFORMED DOSING GUIDELINES IN PEDIATRIC CLINICAL CARE – INITIATION AND DRUG PRIORITIZATION

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Introduction With approximately 50% of the drugs being prescribed off-label, the pediatric population is in need for an innovative approach to establish harmonized, best evidence-based dosing guidelines. Physiologically-based pharmacokinetic (PBPK) modelling is a valuable approach to predict drug pharmacokinetics (PK) and to support dosing. As a first step to implement PBPK-informed dosing in pediatric clinical care, we aimed to identify drugs suitable to verify the PBPK approach and prioritize drugs in need of model-informed dosing.

Methods To select a drug, it required to be listed on: 1. the Model List of Essential Medicines for Children (EMLc) of the WHO and on 2. the Dutch Pediatric Formulary (DPF). Also, a Simcyp® PBPK compound model had to be available. The level of evidence of the dosing recommendations in the DPF, the availability of pediatric pharmacokinetic data, and the opinion of clinicians on the relevance of the drug were reviewed for further prioritization.

Results Of all drugs on the EMLc, 199 are listed in the DPF. For 76 of them, a Simcyp® compound model is available, either directly in the software, its repository, or from scientific literature. Eleven drugs have sufficient PK data to verify the PBPK modeling approach. For 48 drugs, we identify a moderate to high priority for a model-informed dose.

Conclusions This work now provides input for the next steps which include verification of PBPK model performance in pediatrics and subsequent PBPK modelling to establish dosing guidelines. A joint effort and an internationally accessible platform are needed to share information on pediatric PBPK modelling to eventually implement model-informed doses in clinical practice.

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7 COLLABORATION IN NEONATAL AND PAEDIATRIC CLINICAL PHARMACOLOGY: INVOLVING MEDICAL STUDENTS WITHIN (INTER)NATIONAL CLINICAL TRIAL NETWORKS

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Introduction Between 50 and 96% of drugs prescribed to neonatal and paediatric populations are used off-label, creating a clear need for clinical pharmacology studies and subsequent labelling. Key to the successful future of paediatric drug development is creating a collaborative community of professionals focusing on neonatal/paediatric clinical pharmacology. Offering the opportunity for students to participate in a pan-European project such as conect4children (c4c) may enhance their enthusiasm for the field of neonatal/paediatric clinical pharmacology. The primary objective of the concept is to evaluate the motivations and barriers medical students encounter when volunteering in neonatal/paediatric clinical pharmacology and to evaluate the role their tutors play.

Methods A systematic approach to volunteering in this area includes the definition of learning objectives and activities. Conceptual subjects are students and tutors of undergraduate medicine, in the 4th - 6th year, with interest in the field. The c4c Young Investigators Community (YIC) will be used as a platform to interact with established investigators in order to reach the primary objective.

Results Student activities include taking online training courses such as Good Clinical Practice (GCP), translating documents into local languages, actively participating in national/international meetings, and communicating with other healthcare professionals and/or the general public. Investing into involving a younger generation also aids the sustainability of international and clinical trial networks.

Conclusions The concept of medical students volunteering in neonatal and paediatric clinical pharmacology is feasible, motivating for tutors and supports clinical

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