

Activity Outline
FDA Grand Rounds: Perinatal Health Center of Excellence: Development and Validation of Predictive Systems
July 11, 2019
WO 32: 1325

Activity Coordinator
Devin Thomas
Devin.Thomas@fda.hhs.gov

Series Description

The FDA Grand Rounds is webcast monthly to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description

FDA has recognized the need for coordinated research to address public health needs during the perinatal period, which includes the health of the mother, premature infants, and newborns as well as development throughout childhood. To that end, FDA's National Center for Toxicological Research (NCTR) established FDA's virtual Perinatal Health Center of Excellence (PHCE) to address the special public health needs of these important and understudied populations. For example, many FDA-regulated products given to newborns and infants - or provided to pregnant mothers - haven't been studied extensively in such populations. This has left knowledge gaps about their safety, efficacy, or potential toxicity. Environmental exposure through foods and pre-existing conditions are another area where vast knowledge gaps exist. Infants consume more food per kilogram of body weight than any other age group, resulting in the potential for higher dietary exposures to chemicals. And there may also be maternal transfer to the infant from environmental exposures through foods, including breast milk.

To tackle these regulatory science issues that FDA faces, studies will be planned and conducted across the agency's product centers. PHCE-funded research includes *in silico* models, stem cell systems and other *in vitro* models, laboratory animal studies, translational and clinical studies, mathematical modeling, bioanalytical chemistry, exposure science, and bioinformatics targeting the perinatal period. A PHCE funded project to investigate opioid-induced neural tube defects in a mouse model will be highlighted. This project seeks to clarify the link between maternal toxicity and embryo-fetal development following opioid exposure. The results may improve health communications (i.e. label change) that would help pregnant women and their health-care professionals make more informed decisions regarding the risk of opioid exposure during early development.

References

- Cohen-Wolkowicz M, Watt KM, Zhou C, Bloom BT, Poindexter B, Castro L, et al. Developmental pharmacokinetics of piperacillin and tazobactam using plasma and dried blood spots from infants. *Antimicrob Agents Chemother.* 2014;58(5):2856-65. doi: 10.1128/AAC.02139-13. PubMed PMID: 24614369; PubMed Central PMCID: PMC3993246.
- Troutman JA, Sullivan MC, Carr GJ, Fisher J. Development of growth equations from longitudinal studies of body weight and height in the full term and preterm neonate: From birth to four years postnatal age. *Birth Defects Res.* 2018;110(11):916-32. doi: 10.1002/bdr2.1214. PubMed PMID: 29536674; PubMed Central PMCID: PMC6030425.

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:

- Describe the goals and priority areas of the PHCE.
- List of key physiology parameters for development of a preterm and neonate PBPK model.
- List challenges in collecting plasma samples and predicting drug plasma concentrations in neonates using a PBPK model.
- Explain (qualitatively) likely sources responsible for the observed variability in measured plasma drug concentrations.

Target Audience

This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 July 11, 2019

Time	Topic	Speaker
12:00 - 1:00 PM	Perinatal Health Center of Excellence: Development and Validation of Predictive Systems	Amy Inselman, PhD

Continuing Education Accreditation



JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.



IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-012-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit

Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Inselman, Amy, PhD, Staff Fellow, National Center for Toxicological Research - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- KEMPF, LUCAS, MD - nothing to disclose
- Lee, Christine, PharmD, , PhD, General Health Scientist, FDA - nothing to disclose
- Wheelock, Leslie, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and Accreditation Team

- ▣ Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLDD - nothing to disclose
- ▣ Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLDD - nothing to disclose
- ▣ Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLDD - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.